

US3592075 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:53:27

All time stamps listed in this document are displayed in GMT

US3592075

Form: Participant Creation

Data signed: (b) (4) 25 Mar 2021 20:12:17

Generated On: 11 Aug 2021 22:53:27

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[Participant ID](#)

US3592075

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

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US3592075

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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 16:07:00

Generated On: 11 Aug 2021 22:53:27

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
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 16:07:00

Generated On: 11 Aug 2021 22:53:27

Date of Informed Consent ( <i>dd MMM yyyy</i> )	8 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input 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 16:07:00

Generated On: 11 Aug 2021 22:53:27

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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 16:07:01

Generated On: 11 Aug 2021 22:53:27

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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 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
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 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	HEARING LOSS RIGHT EAR
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 (3)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	8 AUG 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)	AUG 2020
Start Year (derived)	2020
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 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
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 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	HYPERGLYCEMIA
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
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 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	ESTROGEN DEFICIENCY
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 (7)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	OSTEOARTHRITIS BILATERAL THUMBS, LEFT KNEE
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 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	DEGENERATIVE DISC DISEASE
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 (9)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	INJURED LEFT KNEE
Start date (dd MMM yyyy)	03 UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
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 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	EDEMA LEFT LOWER LEG
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2020
Start Year (derived)	2020
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 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	IDIOPATHIC NEUROPATHY BILATERAL LEGS SENSORY
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Condition	IDIOPATHIC NEUROPATHY BILATERAL FEET
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 AUG 2020
Time of assessment (00:00-23:59)	13:48 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 13:48
Height (xxx.x)	161.0 cm
Weight (xxx.x)	92.3 kg
BMI (xxx.x)	35.60819 kg/m <sup>2</sup>
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 16:07:01

Generated On: 11 Aug 2021 22:53:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 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 16:07:00

Generated On: 11 Aug 2021 22:53:27

Date of assessment (dd MMM yyyy) 8 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2009

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 16:07:01

Generated On: 11 Aug 2021 22:53:27

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**Occupational Risk**

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**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 ☒

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**Specify**

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**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 16:07:01

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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 16:07:01

Generated On: 11 Aug 2021 22:53:27

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 185320

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

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 16:07:01

Generated On: 11 Aug 2021 22:53:27

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)	8 AUG 2020
Time of assessment (00:00-23:59)	13:57 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 13:57
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 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 16:07:01

Generated On: 11 Aug 2021 22:53:27

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)	8 AUG 2020
Time of assessment (00:00-23:59)	16:04 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 16:04
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 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 16:07:01

Generated On: 11 Aug 2021 22:53:27

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 16:07:01

Generated On: 11 Aug 2021 22:53:27

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) 8 AUG 2020

What was the treatment time? (00:00-23:59) 15:33 (24 HR)

Treatment Date and Time (derived) 8 AUG 2020 15:33

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 16:07:01

Generated On: 11 Aug 2021 22:53:27

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

Collection date (dd MMM yyyy)	8 AUG 2020
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Collection time (00:00-23:59)	15:14 (24 HR)
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Collection date and time (derived)	8 AUG 2020 15:14
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)			8 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:58	8 AUG 2020 14:58
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

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 22:53:27

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

08 AUG 2020 16:08

PC Open Date & Time

08 AUG 2020 15:53

PC Close Date & Time

08 AUG 2020 18:23

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**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

08 AUG 2020 19:18

PC Close Date & Time

09 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 20:49

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

10 AUG 2020 21:39

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**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

97.7 °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

11 AUG 2020 20:08

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 23:33

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**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

97.7 °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

13 AUG 2020 17:33

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

15 AUG 2020 00:24

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**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

08 AUG 2020 16:09

PC Open Date & Time

08 AUG 2020 15:53

PC Close Date & Time

08 AUG 2020 18:23

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**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

08 AUG 2020 19:18

PC Close Date & Time

09 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**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

09 AUG 2020 20:49

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**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

10 AUG 2020 21:40

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**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

11 AUG 2020 20:09

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**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

12 AUG 2020 23:34

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**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

13 AUG 2020 17:33

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**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

15 AUG 2020 00:24

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**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 ☐

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 16:09
PC Open Date & Time	08 AUG 2020 15:53
PC Close Date & Time	08 AUG 2020 18:23

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**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 ☐

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 AUG 2020 19:18

PC Close Date & Time

09 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:50
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 21:40
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 20:09
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 23:34
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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

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EAB) (1725)



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 17:34
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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 ☒

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 00:25
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3592075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:07:00

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592075

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:07:00

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:07:00

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592075

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:07:00

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:18:59

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3592075

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:18:59

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 SEP 2020
Time of assessment (00:00-23:59)	11:53 (24 HR)
Vital Signs Date and Time (derived)	05 SEP 2020 11:53
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

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)	5 SEP 2020
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 12:55
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3592075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 SEP 2020

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

US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

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) 5 SEP 2020

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

Treatment Date and Time (derived) 5 SEP 2020 12:23

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

US3592075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 SEP 2020
Collection time (00:00-23:59)	12:15 (24 HR)
Collection date and time (derived)	5 SEP 2020 12:15

US3592075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)			5 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:00	5 SEP 2020 12:00
Nasopharyngeal Swab 2	No		



US3592075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:07:01

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:56

PC Open Date & Time

05 SEP 2020 12:43

PC Close Date & Time

05 SEP 2020 15:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**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

05 SEP 2020 16:08

PC Close Date & Time

06 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	06 SEP 2020 17:35
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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**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

96.7 °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

07 SEP 2020 18:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	08 SEP 2020 12:00
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 16:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**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

98.0 °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

11 SEP 2020 09:35

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**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

97.7 °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 SEP 2020 00:42

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**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

05 SEP 2020 12:56

PC Open Date & Time

05 SEP 2020 12:43

PC Close Date & Time

05 SEP 2020 15:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**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

05 SEP 2020 16:08

PC Close Date & Time

06 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**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

06 SEP 2020 17:36

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**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

07 SEP 2020 18:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**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

08 SEP 2020 12:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**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

09 SEP 2020 16:01

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**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

11 SEP 2020 09:35

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**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

12 SEP 2020 00:42

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**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 ☐

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 12:57
PC Open Date & Time	05 SEP 2020 12:43
PC Close Date & Time	05 SEP 2020 15:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**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 ☐

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 16:08

PC Close Date & Time

06 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**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 ☒

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 17:36
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 18:11
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**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 ☒

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:01
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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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US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 16:01
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 09:36
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 00:43
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

PC Time Stamp

13 SEP 2020 00:00

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 14 SEP 2020 02:03

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:27

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 SEP 2020 00:00
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:53:27

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 SEP 2020 02:04
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3592075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:18:59

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592075

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:18:59

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:48:45

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3592075

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:48:45

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:07:00

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592075

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:07:00

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:07:02

Generated On: 11 Aug 2021 22:53:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:07:02

Generated On: 11 Aug 2021 22:53:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 13:22
Temperature (xxx.x)	99.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:07:02

Generated On: 11 Aug 2021 22:53:27

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.*

US3592075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:07:02

Generated On: 11 Aug 2021 22:53:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	13:38 (24 HR)
Collection date and time (derived)	7 OCT 2020 13:38

US3592075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:07:02

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

<b>TIMEPOINT</b>	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	10 OCT 2020 08:59:15
Patient Cloud Open Date & Time	08 OCT 2020 00:01
Patient Cloud Close Date & Time	12 OCT 2020 23:59

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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 <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	17 OCT 2020 22:13:33
Patient Cloud Open Date & Time	15 OCT 2020 00:01
Patient Cloud Close Date & Time	19 OCT 2020 23:59

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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	24 OCT 2020 13:21:03
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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	07 NOV 2020 12:00:22
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 15:02:11

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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

20 NOV 2020 08:42:56

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 15:46:56
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 12:18:12
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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	09 DEC 2020 12:00:41
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 11:03:34

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 12:36:55

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you 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	28 DEC 2020 12:51:53
Patient Cloud Open Date & Time	28 DEC 2020 00:01
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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

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US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 JAN 2021 00:02:08
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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

13 JAN 2021 15:56:03

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 20:26:06
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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

26 JAN 2021 13:44:47

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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	03 FEB 2021 20:35:44
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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	17 FEB 2021 13:12:23
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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

22 FEB 2021 00:01:56

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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

01 MAR 2021 14:03:54

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 17:27:40

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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

19 MAR 2021 10:22:00

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

<b>TIMEPOINT</b>	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	24 MAR 2021 12:00:33
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 16:03:34

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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	09 APR 2021 13:05:10
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 12:00:21
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 APR 2021 14:22:18
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

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US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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17 SEP 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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24 SEP 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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01 OCT 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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08 OCT 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 OCT 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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25 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

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US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 NOV 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

20 DEC 2021 00:01

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24 DEC 2021 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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31 DEC 2021 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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 ☐

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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14 JAN 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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21 JAN 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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 ☐

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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04 FEB 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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 <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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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07 FEB 2022 00:01

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11 FEB 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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[Patient Cloud Open Date & Time](#)

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14 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 FEB 2022 23:59

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US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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 ☐

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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25 FEB 2022 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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 ☐

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 FEB 2022 00:01

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04 MAR 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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07 MAR 2022 00:01

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11 MAR 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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14 MAR 2022 00:01

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18 MAR 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**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 ☐

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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21 MAR 2022 00:01

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25 MAR 2022 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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[Patient Cloud Open Date & Time](#)

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28 MAR 2022 00:01

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01 APR 2022 23:59

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US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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08 APR 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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15 APR 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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18 APR 2022 00:01

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22 APR 2022 23:59

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US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:53:27**

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

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[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

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US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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09 MAY 2022 00:01

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13 MAY 2022 23:59

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US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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16 MAY 2022 00:01

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20 MAY 2022 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 MAY 2022 00:01

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27 MAY 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 663

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:53:27**

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 JUN 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

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**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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"/>

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3592075

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:53:27

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		03 MAR 2021 13:40:48

US3592075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:43:50

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592075

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:43:50

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592075

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

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

SUBJECT WAS IN  
CONVALESCENT PERIOD  
DURING THIS SC WINDOW.



US3592075

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592075

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 07:10:57

Generated On: 11 Aug 2021 22:53:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 MAR 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 13:10
Temperature (xxx.x)	36.7 C
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)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592075

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

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.*

US3592075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 MAR 2021

Collection time (00:00-23:59)

13:26 (24 HR)

Collection date and time (derived)

3 MAR 2021 13:26

US3592075

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3592075

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:10:57

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592075

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:10:57

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

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*

**US3592075**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:53:27**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Date of Contact	28 DEC 2020
Time of Contact	08:05
Date and Time of Contact (derived)	28 DEC 2020 08:05
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>

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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"/>

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 DEC 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 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 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 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 ☐

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 DEC 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"/>

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 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 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 DEC 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 type="radio"/>
	Mild	<input checked="" 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 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 DEC 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 type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input type="radio"/>
	Mild <input checked="" 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 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 type="radio"/>
	Mild	<input checked="" 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 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 DEC 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 type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input type="radio"/>
	Mild <input checked="" 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 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 DEC 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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 (6)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 type="radio"/>
	Mild	<input checked="" 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 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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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Form: Symptom Log (7)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

Date	29 DEC 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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 (7)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

Date	30 DEC 2020
------	-------------

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

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

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

Temperature	98.5 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 type="radio"/>
	Moderate <input checked="" 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 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 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 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

Date	31 DEC 2020
------	-------------

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

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

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 (9)

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Generated On: 11 Aug 2021 22:53:27

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" 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) 25 Mar 2021 20:14:31

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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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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 28 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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	1 JAN 2021
------	------------

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

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

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

Temperature	98.5 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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Form: Symptom Log (10)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" 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) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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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Form: Symptom Log (11)

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Generated On: 11 Aug 2021 22:53:27

	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	2 JAN 2021
------	------------

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

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

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

Temperature	98.9 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 (11)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 type="radio"/>
	Mild	<input checked="" 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 (11)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 (12)

Data signed: (b) (4) 25 Mar 2021 20:14:31

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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 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) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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	3 JAN 2021
------	------------

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 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 (12)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" 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 28 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 (13)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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	4 JAN 2021
------	------------

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

O2 Saturation	91 %
---------------	------

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 (13)

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Generated On: 11 Aug 2021 22:53:27

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



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Form: Symptom Log (13)

Data signed: (b) (4) 25 Mar 2021 20:14:31

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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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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 28 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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	5 JAN 2021
------	------------

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

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

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

Temperature	99.1 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 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 (14)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

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Form: Symptom Log (14)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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 28 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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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Form: Symptom Log (15)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

Date	6 JAN 2021
------	------------

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

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

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 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 (15)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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) 25 Mar 2021 20:14:31

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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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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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Form: Symptom Log (16)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

Symptom Day

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

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Form: Symptom Log (16)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

Date	7 JAN 2021
------	------------

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

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

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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Form: Symptom Log (16)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

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Form: Symptom Log (16)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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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Form: Symptom Log (17)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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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Form: Symptom Log (17)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

Date	8 JAN 2021
------	------------

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

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

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

Temperature	98.2 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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Form: Symptom Log (17)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 (17)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

Symptom Day

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

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Form: Symptom Log (18)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

Date	9 JAN 2021
------	------------

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 28 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 28 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

Date	10 JAN 2021
------	-------------

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

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

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

Temperature	98.4 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 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 28 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 28 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 JAN 2021
------	-------------

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 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 28 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

	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 28 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Date of Visit 28 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 28 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒  
Nasal Swab ☐  
Saliva Test ☐  
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 4 JAN 2021

End Date 4 JAN 2021

Oxygen Saturation 91 %

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

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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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Mar 2021 20:12:18

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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 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

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 28 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 25 Mar 2021 20:14:31

Generated On: 11 Aug 2021 22:53:27

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 DEC 2020
Day 5	No	
Day 7	No	
Day 9	Yes	05 JAN 2021
Day 14	Yes	10 JAN 2021
Day 21	Yes	17 JAN 2021
Day 28	Yes	29 JAN 2021

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 DEC 2020
Time of assessment (00:00-23:59)	16:32 (24 HR)
Vital Signs Date and Time (derived)	28 DEC 2020 16:32
Height (xxx.x)	161.0 cm
Weight (xxx.x)	92.3 kg
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 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: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 DEC 2020

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28



US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JAN 2021
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 16:45
Height (xxx.x)	161.0 cm
Weight (xxx.x)	93.5 kg
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 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) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JAN 2021

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

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Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 JAN 2021

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

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

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

Visit date (dd MMM yyyy)	1 FEB 2021
--------------------------	------------

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

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

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

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Height	ND - Not Done
Weight	94.4 kg
BMI (xxx.x)	

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Height	ND - Not Done
Weight	94.4 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)	1 FEB 2021
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 13:32
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3592075

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Height	ND - Not Done
Weight	94.4 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)	1 FEB 2021
Time of assessment (00:00-23:59)	14:31 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 14:31
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG



US3592075

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

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

1 FEB 2021

---

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

---

US3592075

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

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

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) 1 FEB 2021

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

Treatment Date and Time (derived) 1 FEB 2021 13:59

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

US3592075

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00-23:59)	13:37 (24 HR)
Collection date and time (derived)	1 FEB 2021 13:37

US3592075

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00 - 23:59)	13:39
Collection Date and Time (derived)	1 FEB 2021 13:39

US3592075

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

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

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*

US3592075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

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

US3592075

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29



US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

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)	3 MAR 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 13:10
Temperature (xxx.x)	36.7 C
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)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

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)	3 MAR 2021
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 14:22
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3592075

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 MAR 2021

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

US3592075

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

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) 3 MAR 2021

What was the treatment time? (00:00-23:59) 13:50 (24 HR)

Treatment Date and Time (derived) 3 MAR 2021 13:50

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

What was the frequency of the study treatment dosing? ONCE

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

US3592075

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592075

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:14:33

Generated On: 11 Aug 2021 22:53:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592075

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 07:10:57

Generated On: 11 Aug 2021 22:53:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57



US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 07:10:57

Generated On: 11 Aug 2021 22:53:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 APR 2021
Time of assessment (00:00-23:59)	09:22 (24 HR)
Vital Signs Date and Time (derived)	1 APR 2021 09:22
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)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592075

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 07:10:57

Generated On: 11 Aug 2021 22:53:27

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.*

US3592075

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 07:10:56

Generated On: 11 Aug 2021 22:53:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 APR 2021
Collection time (00:00-23:59)	09:27 (24 HR)
Collection date and time (derived)	1 APR 2021 09:27

US3592075

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 25 Mar 2021 20:12:17

Generated On: 11 Aug 2021 22:53:27

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 07:10:56

Generated On: 11 Aug 2021 22:53:27

AEID	
Adverse event	SWOLLEN RIGHT EYE
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)	23 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 (1)

Data signed: (b) (4) 28 Apr 2021 07:10:56

Generated On: 11 Aug 2021 22:53:27

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	_____ _____

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 07:10:56

Generated On: 11 Aug 2021 22:53:27

AEID	USA-US103-2021-MRNA-1273-P30 1000003
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)	23 DEC 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)	11 JAN 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"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 07:10:56

Generated On: 11 Aug 2021 22:53:27

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	True
Concomitant Medication	False
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	SUBJECT REPORTED BEING EXPOSED TO A COVID POSITIVE INDIVIDUAL ON 15 NOV 2020 FOR THE LENGTH OF 3 DAYS. NO OTHER CONFIRMED EXPOSURE AFTER THAT DATE.



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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 07:10:56

Generated On: 11 Aug 2021 22:53:27

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 (3)

Data signed: (b) (4) 28 Apr 2021 07:10:56

Generated On: 11 Aug 2021 22:53:27

AEID

Adverse event

WORSENING OF  
HYPERTENSION

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)

10 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 SEP 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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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 07:10:56

Generated On: 11 Aug 2021 22:53:27

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)	

US3592075

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 07:10:56

Generated On: 11 Aug 2021 22:53:27

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	5 SEP 2020
Start time (00:00-23:59)	17:00 (24 HR)
AE start date and time (derived)	5 SEP 2020 17:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 SEP 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 07:10:56

Generated On: 11 Aug 2021 22:53:27

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

---

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

Yes ☒

No ☐

---

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

---

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Name of Medication PAROXETINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	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 2005	
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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Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2006	
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 (3)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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Name of Medication DILTIAZEM

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS BILATERAL  
THUMBS, LEFT KNEE

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	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 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 (5)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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Name of Medication OXYBUTYNIN

Prophylaxis Yes ☐  
No ☒

Indication OVERACTIVE BLADDER

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (6)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	30 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HEADACHE
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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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)	5 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	8 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF  
HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 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 (9)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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Name of Medication MARCAINE

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS LEFT KNEE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INTRA ARTICULAR
Start date (dd MMM yyyy)	7 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)		7 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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Name of Medication XYLOCAINE

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS LEFT KNEE

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INTRA ARTICULAR
Start date (dd MMM yyyy)	7 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)		7 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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Name of Medication CELESTONE

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS LEFT KNEE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INTRA ARTICULAR
Start date (dd MMM yyyy)	7 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)		7 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 25 Mar 2021 20:12:18

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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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US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	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)		25 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)		25 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"/>

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Name of Medication ZITHROMAX

Prophylaxis Yes ☐  
No ☒

Indication SWOLLEN RIGHT EYE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	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)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Name of Medication ZITHROMAX

Prophylaxis Yes ☐  
No ☒

Indication SWOLLEN RIGHT EYE

Dose per administration 250

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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US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	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)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

Name of Medication POLYMYXIN B DROPS

Prophylaxis Yes ☐  
No ☒

Indication SWOLLEN RIGHT EYE

Dose per administration 2

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

If dose unit is Other, specify DROPS

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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US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	23 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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 25 Mar 2021 20:12:18

Generated On: 11 Aug 2021 22:53:27

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3592075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 11 Aug 2021 22:53:27

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:53:27

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

US3592075

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:53:27

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 ☐



US3592075

Folder: SAE USA-US103-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

SAEID	USA-US103-2021-MRNA-1273-P301000003
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)	1

US3592075

Folder: SAE USA-US103-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Mar 2021 20:14:32

Generated On: 11 Aug 2021 22:53:27

SAEID	USA-US103-2021-MRNA-1273-P301000003
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)	1
Date of submission (Pre-filled from custom function)	18/FEB/2021 14:36
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

US3592075 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

US3592075

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:53:27**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Feb 2021 16:51:29
User entered 'US3592075'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:55:25

US3592075

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 20:35:54

US3592075

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:36
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:55:26

US3592075

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:36
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Aug 2020 20:35:54

US3592075

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'SCRN'	System	08 Aug 2020 20:35:54



US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered (b) (6) 1955'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:55:27

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered '65'	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User entered 'YEARS'	System	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User entered '65'	System	08 Aug 2020 20:36:20

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered 'Female (F)'	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered 'l'	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 20:36:08



US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:27

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:03
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 20:36:08

US3592075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:19
User entered '8 Aug 2020'	(b) (4), (b) (6)	08 Aug 2020 20:36:20



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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User entered 'Aug 2020'	System	08 Aug 2020 20:36:20

US3592075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User entered '2020'	System	08 Aug 2020 20:36:20

US3592075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:19
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	08 Aug 2020 20:36:20

US3592075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 20:36:20

US3592075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:27

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:19
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 20:36:20

US3592075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:19
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 20:36:20

US3592075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:19
User entered 'No (N)'	(b) (4), (b) (6)	08 Aug 2020 20:36:20

US3592075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:55:26



US3592075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User entered 'l'	System	08 Aug 2020 20:36:26

US3592075

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 20:36:26

US3592075

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:53:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:08:42

US3592075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:33
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:14:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:14:08
Data point term sent to Coder	System	11 Aug 2020 14:12:56
User entered 'Seasonal allergies'	(b) (4), (b) (6)	11 Aug 2020 14:12:09

US3592075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:34
User entered 'un UNK 1960'	(b) (4), (b) (6)	11 Aug 2020 14:12:09

US3592075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:36
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:12:09

US3592075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:12:09

US3592075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:40
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:12:09



US3592075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:43
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:12:09

US3592075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 1960'	System	11 Aug 2020 14:12:09

US3592075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '1960'	System	11 Aug 2020 14:12:09

US3592075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:12:09

US3592075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:12:09

US3592075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:48
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness unilateral, LLT: Hearing loss unilateral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:16:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:16:09
Data point term sent to Coder	System	11 Aug 2020 14:15:00
User entered 'Hearing loss right ear'	(b) (4), (b) (6)	11 Aug 2020 14:14:49

US3592075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:52
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 14:14:49

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:54
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:14:49



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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:14:49

US3592075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:10:58
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:49

US3592075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:00
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:14:49

US3592075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 2015'	System	11 Aug 2020 14:14:49

US3592075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2015'	System	11 Aug 2020 14:14:49

US3592075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:14:49

US3592075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:14:49

US3592075

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:08
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)	25 Aug 2020 19:00:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 19:00:33
Data point term sent to Coder	System	25 Aug 2020 18:59:50
User entered 'overactive bladder'	(b) (4), (b) (6)	25 Aug 2020 18:59:19



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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:10
User entered '8 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:59:19

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:11
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:59:19

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:59:19

US3592075

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:17
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:59:19

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:18
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:59:19

US3592075

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Aug 2020'	System	25 Aug 2020 18:59:19

US3592075

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2020'	System	25 Aug 2020 18:59:19

US3592075

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Aug 2020 18:59:19



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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Aug 2020 18:59:19

US3592075

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:23
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:18:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:18:06
Data point term sent to Coder	System	11 Aug 2020 14:17:03
User entered 'Hypertension'	(b) (4), (b) (6)	11 Aug 2020 14:16:25

US3592075

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:26
User entered 'un UNK 1990'	(b) (4), (b) (6)	11 Aug 2020 14:16:25

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:29
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:16:25

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:16:25

US3592075

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:34
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:16:25

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:36
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:16:25

US3592075

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 1990'	System	11 Aug 2020 14:16:25



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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '1990'	System	11 Aug 2020 14:16:25

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:16:25

US3592075

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:16:25

US3592075

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:18:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 14:18:07
Data point term sent to Coder	System	11 Aug 2020 14:18:03
User entered 'Hyperglycemia'	(b) (4), (b) (6)	11 Aug 2020 14:17:20

US3592075

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:45
User entered 'un UNK 1993'	(b) (4), (b) (6)	11 Aug 2020 14:17:20

US3592075

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:48
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:17:20

US3592075

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:17:20

US3592075

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:17:20



US3592075

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:11:54
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:17:20

US3592075

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 1993'	System	11 Aug 2020 14:17:20

US3592075

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '1993'	System	11 Aug 2020 14:17:20

US3592075

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:17:20

US3592075

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:17:20

US3592075

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:01
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Oestrogen deficiency, LLT: Estrogen deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:28:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:28:08
Data point term sent to Coder	System	11 Aug 2020 14:27:09
User entered 'Estrogen deficiency'	(b) (4), (b) (6)	11 Aug 2020 14:26:31

US3592075

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:03
User entered 'un UNK 2009'	(b) (4), (b) (6)	11 Aug 2020 14:26:31

US3592075

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:05
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:26:31



US3592075

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:26:31

US3592075

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:26:31

US3592075

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:12
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:26:31

US3592075

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 2009'	System	11 Aug 2020 14:26:31

US3592075

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2009'	System	11 Aug 2020 14:26:31

US3592075

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:26:31

US3592075

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:26:31

US3592075

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 07:04:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 07:04:11
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	06 Oct 2020 06:16:08
' (Site from DM).		
Data point term sent to Coder	System	30 Sep 2020 21:41:21
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	30 Sep 2020 21:41:02
' answered with 'term updated' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	30 Sep 2020 21:40:57
User entered 'OSTEOARTHRITIS BILATERAL THUMBS, LEFT KNEE' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 21:40:57
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	25 Sep 2020 20:35:50
' (Site from DM).		



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Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 14:30:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 14:30:10
Data point term sent to Coder	System	11 Aug 2020 14:29:13
User entered 'Osteoarthritis'	(b) (4), (b) (6)	11 Aug 2020 14:28:21

US3592075

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:19
User entered 'un UNK 2010'	(b) (4), (b) (6)	11 Aug 2020 14:28:21

US3592075

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:21
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:28:21

US3592075

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:28:21

US3592075

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:27
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:28:21

US3592075

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:28
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:28:21

US3592075

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 2010'	System	11 Aug 2020 14:28:21

US3592075

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2010'	System	11 Aug 2020 14:28:21



US3592075

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:28:21

US3592075

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:28:21

US3592075

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 14:31:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 14:31:08
Data point term sent to Coder	System	11 Aug 2020 14:30:14
User entered 'Degenerative disc disease'	(b) (4), (b) (6)	11 Aug 2020 14:30:12

US3592075

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:36
User entered 'un UNK 2018'	(b) (4), (b) (6)	11 Aug 2020 14:30:12

US3592075

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:39
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:30:12

US3592075

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:30:12

US3592075

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:41
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:30:12

US3592075

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:43
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:30:12



US3592075

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:53:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 2018'	System	11 Aug 2020 14:30:12

US3592075

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2018'	System	11 Aug 2020 14:30:12

US3592075

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:30:12

US3592075

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	11 Aug 2020 14:30:12

US3592075

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:53:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:32:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:32:11
Data point term sent to Coder	System	11 Aug 2020 14:31:15
User entered 'Uterine fibroids'	(b) (4), (b) (6)	11 Aug 2020 14:30:30

US3592075

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'un UNK 2009'	(b) (4), (b) (6)	11 Aug 2020 14:30:30

US3592075

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:30:30

US3592075

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:30:30



US3592075

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'un UNK 2009'	(b) (4), (b) (6)	11 Aug 2020 14:30:30

US3592075

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:30:30

US3592075

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 2009'	System	11 Aug 2020 14:30:30

US3592075

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2009'	System	11 Aug 2020 14:30:30

US3592075

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 2009'	System	11 Aug 2020 14:30:30

US3592075

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2009'	System	11 Aug 2020 14:30:30

US3592075

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:53:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:34:06
User closed query 'Please review, appears to be a surgical procedure prior to entering in study. May need to enter in Concomitant Procedure.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 16:34:00
Query 'Please review, appears to be a surgical procedure prior to entering in study. May need to enter in Concomitant Procedure.' answered with 'Per crf guidelines we only record procedures performed after the first dose of study vaccination on concomitant procedures page.' (Site from CRA).	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 21:02:11
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 20:13:00
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:12:49
User opened query 'Please review, appears to be a surgical procedure prior to entering in study. May need to enter in Concomitant Procedure.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 20:08:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:32:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:32:10
Data point term sent to Coder	System	11 Aug 2020 14:31:15
User entered 'Total hysterectomy'	(b) (4), (b) (6)	11 Aug 2020 14:30:53

US3592075

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'un UNK 2009'	(b) (4), (b) (6)	11 Aug 2020 14:30:53



US3592075

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:30:53

US3592075

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:30:53

US3592075

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'un UNK 2009'	(b) (4), (b) (6)	11 Aug 2020 14:30:53

US3592075

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:30:53

US3592075

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 2009'	System	11 Aug 2020 14:30:53

US3592075

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2009'	System	11 Aug 2020 14:30:53

US3592075

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 2009'	System	11 Aug 2020 14:30:53

US3592075

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2009'	System	11 Aug 2020 14:30:53



US3592075

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Knee injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:44:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:44:33
Data point term sent to Coder	System	25 Aug 2020 19:00:56
User entered 'injured left knee'	(b) (4), (b) (6)	25 Aug 2020 19:00:40

US3592075

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:34:31
User closed query 'Please review with subject. Screening is being done 08 Aug 2020, we should at least get the month as this is too close for unknown dates.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 16:34:28
Query 'Please review with subject. Screening is being done 08 Aug 2020, we should at least get the month as this is too close for unknown dates.' answered with 'contacted patient for more info, updated start date.' (Site from CRA).	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 21:43:29
User entered '03 UNK 2020' reason for change: New Information	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 21:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 20:13:05
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:12:49
User opened query 'Please review with subject. Screening is being done 08 Aug 2020, we should at least get the month as this is too close for unknown dates.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 20:10:12
User entered 'un UNK 2020'	(b) (4), (b) (6)	25 Aug 2020 19:00:40

US3592075

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:00:40

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Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:00:40

US3592075

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:00:40

US3592075

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:00:40

US3592075

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 2020'	System	25 Aug 2020 19:00:40

US3592075

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2020'	System	25 Aug 2020 19:00:40



US3592075

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Aug 2020 19:00:40

US3592075

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Aug 2020 19:00:40

US3592075

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
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)	25 Aug 2020 19:02:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:02:40
Data point term sent to Coder	System	25 Aug 2020 19:02:01
User entered 'depression'	(b) (4), (b) (6)	25 Aug 2020 19:01:22

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Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'un UNK 1985'	(b) (4), (b) (6)	25 Aug 2020 19:01:22

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Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:01:22

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Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:01:22

US3592075

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:01:22

US3592075

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 19:01:22



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Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 1985'	System	25 Aug 2020 19:01:22

US3592075

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '1985'	System	25 Aug 2020 19:01:22

US3592075

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Aug 2020 19:01:22

US3592075

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Aug 2020 19:01:22

US3592075

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Lower leg edema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 20:34:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 20:34:39
Data point term sent to Coder	System	25 Sep 2020 16:31:30
User entered 'edema left lower leg'	(b) (4), (b) (6)	25 Sep 2020 16:31:25

US3592075

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'un Feb 2020'	(b) (4), (b) (6)	25 Sep 2020 16:31:25

US3592075

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:31:25

US3592075

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:31:25



US3592075

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:31:25

US3592075

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:31:25

US3592075

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Feb 2020'	System	25 Sep 2020 16:31:25

US3592075

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2020'	System	25 Sep 2020 16:31:25

US3592075

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Sep 2020 16:31:25

US3592075

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Sep 2020 16:31:25

US3592075

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
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)	25 Sep 2020 16:57:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Sep 2020 16:57:42
Data point term sent to Coder	System	25 Sep 2020 16:32:30
User entered 'overactive bladder'	(b) (4), (b) (6)	25 Sep 2020 16:32:02

US3592075

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'un Feb 2020'	(b) (4), (b) (6)	25 Sep 2020 16:32:02



US3592075

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:32:02

US3592075

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:32:02

US3592075

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:32:02

US3592075

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:32:02

US3592075

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Feb 2020'	System	25 Sep 2020 16:32:02

US3592075

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2020'	System	25 Sep 2020 16:32:02

US3592075

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Sep 2020 16:32:02

US3592075

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Sep 2020 16:32:02



US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User closed 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)	26 Jan 2021 07:02:18
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Jan 2021 12:04:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Jan 2021 12:04:47
Data point term sent to Coder	System	22 Jan 2021 15:40:27
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.' answered with 'updated term to include sensory neuropathy ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 15:39:57
Coding entries removed.	(b) (4), (b) (6)	22 Jan 2021 15:39:28
User entered 'IDIOPATHIC NEUROPATHY BILATERAL LEGS sensory' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Jan 2021 15:39:28
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)	14 Jan 2021 05:04:42

US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Unspecified idiopathic peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	05 Dec 2020 20:40:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Dec 2020 20:40:06
Data point term sent to Coder	System	05 Dec 2020 20:39:32
User closed query 'CDM-Coding: For coding purpose, please provide the body location and type to the term, and update the term accordingly.' (Site from System).	System	05 Dec 2020 20:39:17
Query 'CDM-Coding: For coding purpose, please provide the body location and type to the term, and update the term accordingly.' answered with 'updated trm ' (Site from System).	(b) (4), (b) (6)	05 Dec 2020 20:39:17
User entered 'IDIOPATHIC NEUROPATHY bilateral legs' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Dec 2020 20:39:10
User opened query 'CDM-Coding: For coding purpose, please provide the body location and type to the term, and update the term accordingly.' (Site from System).	Coder Import (b) (4)	12 Nov 2020 08:25:43
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	06 Nov 2020 15:30:18
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	28 Oct 2020 07:59:42
' (Site from DM).		
Data point term sent to Coder	System	25 Sep 2020 16:33:33
User entered 'idiopathic neuropathy'	(b) (4), (b) (6)	25 Sep 2020 16:33:12

US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'un UNK 1988'	(b) (4), (b) (6)	25 Sep 2020 16:33:12

US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:33:12

US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:33:12

US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:33:12

US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:33:12

US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 1988'	System	25 Sep 2020 16:33:12



US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '1988'	System	25 Sep 2020 16:33:12

US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Sep 2020 16:33:12

US3592075

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	25 Sep 2020 16:33:12

US3592075

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:44:01
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:37:21
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 07:08:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 07:08:47
Data point term sent to Coder	System	01 Oct 2020 23:01:45
User entered 'recurrent upper respiratory infection'	(b) (4), (b) (6)	01 Oct 2020 23:00:57

US3592075

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'un UNK 2014'	(b) (4), (b) (6)	01 Oct 2020 23:00:57

US3592075

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 23:00:57

US3592075

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 23:00:57

US3592075

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 23:00:57



US3592075

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 23:00:57

US3592075

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:53:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 2014'	System	01 Oct 2020 23:00:57

US3592075

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '2014'	System	01 Oct 2020 23:00:57

US3592075

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	01 Oct 2020 23:00:57

US3592075

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	01 Oct 2020 23:00:57

US3592075

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:53:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Dec 2020 20:41:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Dec 2020 20:41:07
Data point term sent to Coder	System	05 Dec 2020 20:40:34
User entered 'IDIOPATHIC NEUROPATHY BILATERAL feet' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Dec 2020 20:39:38
Data point term sent to Coder	System	05 Dec 2020 20:39:33
User entered 'IDIOPATHIC NEUROPATHY bilateral legs'	(b) (4), (b) (6)	05 Dec 2020 20:39:30

US3592075

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'un UNK 1988'	(b) (4), (b) (6)	05 Dec 2020 20:39:30

US3592075

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	05 Dec 2020 20:39:30



US3592075

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:53:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Dec 2020 20:39:30

US3592075

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered empty.	(b) (4), (b) (6)	05 Dec 2020 20:39:30

US3592075

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:53:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:12:49
User entered '0'	(b) (4), (b) (6)	05 Dec 2020 20:39:30

US3592075

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'Jan 1988'	System	05 Dec 2020 20:39:30

US3592075

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:53:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '1988'	System	05 Dec 2020 20:39:30

US3592075

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	05 Dec 2020 20:39:30

US3592075

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered empty.	System	05 Dec 2020 20:39:30

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:32:37



US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered '8 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered '13:48'	(b) (4), (b) (6)	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered '8 Aug 2020 13:48'	System	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered '161.0' cm	(b) (4), (b) (6)	11 Aug 2020 14:32:37
DataPoint set to visible.	System	08 Aug 2020 20:36:26

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered '92.3' kg	(b) (4), (b) (6)	11 Aug 2020 14:32:37
DataPoint set to visible.	System	08 Aug 2020 20:36:26

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
Amendment Manager: User entered '35.60819'	System	16 Sep 2020 23:49:02
User entered '35.6'	System	11 Aug 2020 14:32:37
DataPoint set to visible.	System	08 Aug 2020 20:36:26

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'kg/m2'	System	11 Aug 2020 14:32:37
DataPoint set to visible.	System	08 Aug 2020 20:36:26

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
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)	26 Aug 2020 04:00:37
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 16:22:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:22:04
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 03:58:58
User entered '36.9' C	(b) (4), (b) (6)	11 Aug 2020 14:32:37



US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:22:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:22:04
User entered '78'	(b) (4), (b) (6)	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'bpm'	System	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:22:04
User entered '16'	(b) (4), (b) (6)	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'breaths/min'	System	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:22:04
User entered '144'	(b) (4), (b) (6)	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'mmHg'	System	11 Aug 2020 14:32:37



US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:22:04
User entered '96'	(b) (4), (b) (6)	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User entered 'mmHg'	System	11 Aug 2020 14:32:37

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53

US3592075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53

US3592075

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:03:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:22:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:32:57

US3592075

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:35
User entered '8 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:03:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:22:19
User entered '8 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:32:57

US3592075

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:40
User entered '8 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:37:34

US3592075

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:27

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:40
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:37:34



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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:27

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:40
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	11 Aug 2020 14:37:51
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	11 Aug 2020 14:37:34
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	11 Aug 2020 14:37:34

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:27

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:40
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:37:34

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:40
User entered 'un UNK 2009'	(b) (4), (b) (6)	11 Aug 2020 14:37:34

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:27

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:40
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:37:34

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:37:51
User entered 'un UNK 2009'	(b) (4), (b) (6)	11 Aug 2020 14:37:34

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:53:27

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:40
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:37:34

US3592075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

[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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

**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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

**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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

**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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

[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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

[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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

**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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

[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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

**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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

**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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

US3592075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

**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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

US3592075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

[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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

US3592075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

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 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:38:25



US3592075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered 'l'	(b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:38:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:52
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:38:25

US3592075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:38:42

US3592075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:57
User entered '8 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:38:42

US3592075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[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 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:57
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 14:38:42

US3592075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'VISIT1'	System	11 Aug 2020 14:38:42

US3592075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:24:06
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 20:30:28



US3592075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:27

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:24:06
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:08:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:08:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 20:30:28
User entered '185320' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 20:30:28

US3592075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:27

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:24:06
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 20:30:28

US3592075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:27

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 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:24:06
User closed query 'Per CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 05:08:19
Query 'Per CDM: Please complete this section of the form.' answered with 'section completed ' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 17:31:39
User entered 'No (N)'	(b) (4), (b) (6)	05 Sep 2020 17:31:25
User opened query 'Per CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 13:24:21

US3592075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:27

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 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:24:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Sep 2020 17:31:25

US3592075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:27

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:24:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Sep 2020 17:31:25

US3592075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:27

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:24:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Sep 2020 17:31:25

US3592075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:24:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Sep 2020 17:31:25

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Aug 2020 17:56:19
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Please update accordingly. ' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 18:14:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 18:14:38
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 11:56:09
User entered '161.0' cm	(b) (4), (b) (6)	11 Aug 2020 14:41:09



US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 18:14:38
User entered '92.3' kg	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day . Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Aug 2020 17:56:19
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day . Please update accordingly. ' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 18:14:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 18:14:38
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day . Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 11:56:09
User entered '161.0' cm	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 18:14:38
User entered '92.3' kg	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered '8 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:04
User closed query 'Please confirm Time as it is inconsistent with source.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 16:35:01
Query 'Please confirm Time as it is inconsistent with source.' answered with 'time has been corrected to match source.' (Site from CRA).	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 20:04:16
User entered '13:57' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 20:04:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 20:29:28
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:29:15
User opened query 'Please confirm Time as it is inconsistent with source.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 20:26:02
User entered '13:48'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '8 Aug 2020 13:57'	System	12 Feb 2021 20:04:03
User entered '8 Aug 2020 13:48'	System	11 Aug 2020 14:41:09



US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered '36.9' C	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered '78'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'bpm'	System	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered '16'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'breaths/min'	System	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered '144'	(b) (4), (b) (6)	11 Aug 2020 14:41:09



US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'mmHg'	System	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered '96'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'mmHg'	System	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Aug 2020 17:56:19
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Please update accordingly. ' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 18:14:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 18:14:38
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and VID1 has occurred on the same day . Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 11:56:09
User entered '161.0' cm	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 18:14:38
User entered '92.3' kg	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered '8 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:41:09



US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:19
User closed query 'Please confirm Time of Assessment. Vitals taken 2 times and times are inconsistent with Blood Pressure times.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 16:35:16
Query 'Please confirm Time of Assessment. Vitals taken 2 times and times are inconsistent with Blood Pressure times.' answered with 'time of first BP used since all vitals were done at that time. BP only was repeated at 16:23' (Site from CRA).	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 20:11:38
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:29:15
User opened query 'Please confirm Time of Assessment. Vitals taken 2 times and times are inconsistent with Blood Pressure times.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 20:29:00
User closed 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).	(b) (4), (b) (6)	13 Aug 2020 03:39:19
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:41:25
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 14:41:09
User entered '16:04'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '8 Aug 2020 16:04'	System	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 14:41:16
User entered '97.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:41:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 14:41:09
User entered '97.6' (non-conformant).	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered '69'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'bpm'	System	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered '16'	(b) (4), (b) (6)	11 Aug 2020 14:41:09



US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'breaths/min'	System	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Aug 2020 17:58:50
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'no clinical concerns and improved repeat numbers ' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 19:08:32
User entered '165' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:07:08
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 14:41:09
User entered '178'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'mmHg'	System	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:15
User entered '95' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:07:08
User entered '97'	(b) (4), (b) (6)	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'mmHg'	System	11 Aug 2020 14:41:09

US3592075

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:04:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:41:44

US3592075

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:29:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:04:06
User entered '8 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:41:44

US3592075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 20:36:57



US3592075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:03
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 20:36:57

US3592075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

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 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:03
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 20:36:57

US3592075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 20:36:57

US3592075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:03
User entered '8 Aug 2020'	(b) (4), (b) (6)	08 Aug 2020 20:36:57

US3592075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:03
User entered '15:33'	(b) (4), (b) (6)	08 Aug 2020 20:36:57

US3592075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '8 Aug 2020 15:33'	System	08 Aug 2020 20:36:57

US3592075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:03
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Aug 2020 20:36:57

US3592075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:30:03
User entered 'ONCE'	System	08 Aug 2020 20:36:57



US3592075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 20:36:57

US3592075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:42:07

US3592075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:07
User entered '8 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:42:07

US3592075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:07
User entered '15:14'	(b) (4), (b) (6)	11 Aug 2020 14:42:07

US3592075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '8 Aug 2020 15:14'	System	11 Aug 2020 14:42:07

US3592075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:11
User entered '8 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:42:22

US3592075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Aug 2020 14:42:22

US3592075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:42:22



US3592075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:11
User entered '14:58'	(b) (4), (b) (6)	11 Aug 2020 14:42:22

US3592075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '8 Aug 2020 14:58'	System	11 Aug 2020 14:42:22

US3592075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Aug 2020 14:42:22

US3592075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:11
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:42:22

US3592075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:11
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:42:22

US3592075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered empty.	System	11 Aug 2020 14:42:22

US3592075

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:30:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:42:27

US3592075

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'l'	System	11 Aug 2020 14:42:27



US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:08:15', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'e73838ff-2358-4374-b53c-2787bf2a0991'	System	08 Aug 2020 21:08:38
User entered 'Yes (Y)'	System	08 Aug 2020 21:08:38

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:08:24', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'e73838ff-2358-4374-b53c-2787bf2a0991' User entered '97.6'	System	08 Aug 2020 21:08:38
	System	08 Aug 2020 21:08:38

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:08:28', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'e73838ff-2358-4374-b53c-2787bf2a0991'	System	08 Aug 2020 21:08:38
User entered 'No (N)'	System	08 Aug 2020 21:08:38

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:08:37', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'e73838ff-2358-4374-b53c-2787bf2a0991' User entered '08 Aug 2020 16:08'	System	08 Aug 2020 21:08:38
	System	08 Aug 2020 21:08:38

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Aug 2020 15:53'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Aug 2020 18:23'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 20:36:57



US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Aug 2020 19:18'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 20:36:57



US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 2'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '021e2a35-8777-482f-9fa6-66c081c2ad3c' User entered 'Yes (Y)'	System	10 Aug 2020 01:49:23
	System	10 Aug 2020 01:49:23

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:11', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '021e2a35-8777-482f-9fa6-66c081c2ad3c' User entered '97.8'	System	10 Aug 2020 01:49:23
	System	10 Aug 2020 01:49:23

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:15', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '021e2a35-8777-482f-9fa6-66c081c2ad3c' User entered 'No (N)'	System	10 Aug 2020 01:49:23
	System	10 Aug 2020 01:49:23

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:20', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '021e2a35-8777-482f-9fa6-66c081c2ad3c' User entered '09 Aug 2020 20:49'	System	10 Aug 2020 01:49:23
	System	10 Aug 2020 01:49:23

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 3'	System	08 Aug 2020 20:36:57



US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:39:40', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '508697e3-be7c-43d2-b67e-2415d37e5fad'	System	11 Aug 2020 02:39:57
User entered 'Yes (Y)'	System	11 Aug 2020 02:39:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:39:47', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '508697e3-be7c-43d2-b67e-2415d37e5fad' User entered '97.1'	System	11 Aug 2020 02:39:57
	System	11 Aug 2020 02:39:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:39:50', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '508697e3-be7c-43d2-b67e-2415d37e5fad'	System	11 Aug 2020 02:39:57
User entered 'No (N)'	System	11 Aug 2020 02:39:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:39:55', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '508697e3-be7c-43d2-b67e-2415d37e5fad' User entered '10 Aug 2020 21:39'	System	11 Aug 2020 02:39:57
	System	11 Aug 2020 02:39:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 4'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:08:38', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd1d11238-ae08-490f-a0a8-2ac2c8886d9d' User entered 'Yes (Y)'	System	12 Aug 2020 01:08:58
	System	12 Aug 2020 01:08:58



US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:08:48', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd1d11238-ae08-490f-a0a8-2ac2c8886d9d' User entered '97.7'	System	12 Aug 2020 01:08:58
	System	12 Aug 2020 01:08:58

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:08:51', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd1d11238-ae08-490f-a0a8-2ac2c8886d9d'	System	12 Aug 2020 01:08:58
User entered 'No (N)'	System	12 Aug 2020 01:08:58

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:08:56', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd1d11238-ae08-490f-a0a8-2ac2c8886d9d' User entered '11 Aug 2020 20:08'	System	12 Aug 2020 01:08:58
	System	12 Aug 2020 01:08:58

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 5'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:33:38', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c6a953ac-c9f3-4525-b74e-60709c8c4d0b' User entered 'Yes (Y)'	System	13 Aug 2020 04:33:43
	System	13 Aug 2020 04:33:43

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:33:32', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c6a953ac-c9f3-4525-b74e-60709c8c4d0b' User entered '97.7'	System	13 Aug 2020 04:33:43
	System	13 Aug 2020 04:33:43



US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:33:36', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c6a953ac-c9f3-4525-b74e-60709c8c4d0b' User entered 'No (N)'	System	13 Aug 2020 04:33:43
	System	13 Aug 2020 04:33:43

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:33:42', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c6a953ac-c9f3-4525-b74e-60709c8c4d0b' User entered '12 Aug 2020 23:33'	System	13 Aug 2020 04:33:43
	System	13 Aug 2020 04:33:43

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 6'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:33:23', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '0498d4d7-0aac-4cfd-a829-c8f4dafdf1dc' User entered 'Yes (Y)'	System	13 Aug 2020 22:33:40
	System	13 Aug 2020 22:33:40

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:33:29', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '0498d4d7-0aac-4cf4-a829-c8f4dafdf1dc' User entered '97.7'	System	13 Aug 2020 22:33:40
	System	13 Aug 2020 22:33:40

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:33:33', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '0498d4d7-0aac-4cfd-a829-c8f4dafdf1dc'	System	13 Aug 2020 22:33:40
User entered 'No (N)'	System	13 Aug 2020 22:33:40



US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:33:36', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '0498d4d7-0aac-4cfd-a829-c8f4dafdf1dc' User entered '13 Aug 2020 17:33'	System	13 Aug 2020 22:33:40
	System	13 Aug 2020 22:33:40

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 7'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:17', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ae9908a1-b2d4-4a86-a391-b030aa3d6c73' User entered 'Yes (Y)'	System	15 Aug 2020 05:24:25
	System	15 Aug 2020 05:24:25

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:10', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ae9908a1-b2d4-4a86-a391-b030aa3d6c73' User entered '98.1'	System	15 Aug 2020 05:24:25
	System	15 Aug 2020 05:24:25

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:13', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ae9908a1-b2d4-4a86-a391-b030aa3d6c73'	System	15 Aug 2020 05:24:25
User entered 'No (N)'	System	15 Aug 2020 05:24:25

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:21', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ae9908a1-b2d4-4a86-a391-b030aa3d6c73' User entered '15 Aug 2020 00:24'	System	15 Aug 2020 05:24:25
	System	15 Aug 2020 05:24:25



US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:08:55', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '33d9fc2b-fc7e-4c61-a300-d4d66d0a9a2c'	System	08 Aug 2020 21:09:19
User entered 'None (1)'	System	08 Aug 2020 21:09:19

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:08:58', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '33d9fc2b-fc7e-4c61-a300-d4d66d0a9a2c' User entered 'No (N)'	System	08 Aug 2020 21:09:19
	System	08 Aug 2020 21:09:19

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '33d9fc2b-fc7e-4c61-a300-d4d66d0a9a2c' User entered 'No (N)'	System	08 Aug 2020 21:09:19
	System	08 Aug 2020 21:09:19

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:09', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '33d9fc2b-fc7e-4c61-a300-d4d66d0a9a2c' User entered 'None (1)'	System	08 Aug 2020 21:09:19
	System	08 Aug 2020 21:09:19

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:16', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '33d9fc2b-fc7e-4c61-a300-d4d66d0a9a2c' User entered '08 Aug 2020 16:09'	System	08 Aug 2020 21:09:19
	System	08 Aug 2020 21:09:19



US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Aug 2020 15:53'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Aug 2020 18:23'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26



US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Aug 2020 19:18'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 2'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:28', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '59dfaf33-7f80-4f6e-bfd2-ec222f93fd00'	System	10 Aug 2020 01:49:48
User entered 'None (1)'	System	10 Aug 2020 01:49:48

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:31', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '59dfaf33-7f80-4f6e-bfd2-ec222f93fd00'	System	10 Aug 2020 01:49:48
User entered 'No (N)'	System	10 Aug 2020 01:49:48

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:34', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '59dfaf33-7f80-4f6e-bfd2-ec222f93fd00'	System	10 Aug 2020 01:49:48
User entered 'No (N)'	System	10 Aug 2020 01:49:48



US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:39', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '59dfaf33-7f80-4f6e-bfd2-ec222f93fd00'	System	10 Aug 2020 01:49:48
User entered 'None (1)'	System	10 Aug 2020 01:49:48

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:44', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '59dfaf33-7f80-4f6e-bfd2-ec222f93fd00'	System	10 Aug 2020 01:49:48
User entered '09 Aug 2020 20:49'	System	10 Aug 2020 01:49:48

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 3'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:01', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8b2a8350-5f74-4e5a-b992-663989c739f6'	System	11 Aug 2020 02:40:19
User entered 'None (1)'	System	11 Aug 2020 02:40:19

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:05', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8b2a8350-5f74-4e5a-b992-663989c739f6'	System	11 Aug 2020 02:40:19
User entered 'No (N)'	System	11 Aug 2020 02:40:19

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:08', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8b2a8350-5f74-4e5a-b992-663989c739f6'	System	11 Aug 2020 02:40:19
User entered 'No (N)'	System	11 Aug 2020 02:40:19



US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:11', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8b2a8350-5f74-4e5a-b992-663989c739f6'	System	11 Aug 2020 02:40:19
User entered 'None (1)'	System	11 Aug 2020 02:40:19

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:16', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8b2a8350-5f74-4e5a-b992-663989c739f6'	System	11 Aug 2020 02:40:19
User entered '10 Aug 2020 21:40'	System	11 Aug 2020 02:40:19

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 4'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8277b0d2-38f8-4257-8338-69ee7cdcd2f4'	System	12 Aug 2020 01:09:15
User entered 'None (1)'	System	12 Aug 2020 01:09:15

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8277b0d2-38f8-4257-8338-69ee7cdcd2f4'	System	12 Aug 2020 01:09:15
User entered 'No (N)'	System	12 Aug 2020 01:09:15

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:06', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8277b0d2-38f8-4257-8338-69ee7cdcd2f4'	System	12 Aug 2020 01:09:15
User entered 'No (N)'	System	12 Aug 2020 01:09:15



US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:08', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8277b0d2-38f8-4257-8338-69ee7cdcd2f4'	System	12 Aug 2020 01:09:15
User entered 'None (1)'	System	12 Aug 2020 01:09:15

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:11', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8277b0d2-38f8-4257-8338-69ee7cdcd2f4'	System	12 Aug 2020 01:09:15
User entered '11 Aug 2020 20:09'	System	12 Aug 2020 01:09:15

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 5'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:33:59', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '76ba4d50-b1a3-4a89-8160-9c9724ccb142'	System	13 Aug 2020 04:34:04
User entered 'None (1)'	System	13 Aug 2020 04:34:04

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:33:49', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '76ba4d50-b1a3-4a89-8160-9c9724ccb142'	System	13 Aug 2020 04:34:04
User entered 'No (N)'	System	13 Aug 2020 04:34:04

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:33:52', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '76ba4d50-b1a3-4a89-8160-9c9724ccb142'	System	13 Aug 2020 04:34:04
User entered 'No (N)'	System	13 Aug 2020 04:34:04



US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:33:55', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '76ba4d50-b1a3-4a89-8160-9c9724ccb142'	System	13 Aug 2020 04:34:04
User entered 'None (1)'	System	13 Aug 2020 04:34:04

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:34:01', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '76ba4d50-b1a3-4a89-8160-9c9724ccb142'	System	13 Aug 2020 04:34:04
User entered '12 Aug 2020 23:34'	System	13 Aug 2020 04:34:04

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 6'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:33:40', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5693a5e0-1f0e-42bb-ad09-1ebdcfbb27ae'	System	13 Aug 2020 22:33:56
User entered 'None (1)'	System	13 Aug 2020 22:33:56

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:33:43', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5693a5e0-1f0e-42bb-ad09-1ebdcfbb27ae'	System	13 Aug 2020 22:33:56
User entered 'No (N)'	System	13 Aug 2020 22:33:56

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:33:46', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5693a5e0-1f0e-42bb-ad09-1ebdcfbb27ae'	System	13 Aug 2020 22:33:56
User entered 'No (N)'	System	13 Aug 2020 22:33:56



US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:33:49', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5693a5e0-1f0e-42bb-ad09-1ebdcfbb27ae'	System	13 Aug 2020 22:33:56
User entered 'None (1)'	System	13 Aug 2020 22:33:56

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:33:52', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5693a5e0-1f0e-42bb-ad09-1ebdcfbb27ae' User entered '13 Aug 2020 17:33'	System	13 Aug 2020 22:33:56
	System	13 Aug 2020 22:33:56

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 7'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:30', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '96e363e2-0b5b-476d-b883-bfdda86e3a85'	System	15 Aug 2020 05:24:46
User entered 'None (1)'	System	15 Aug 2020 05:24:46

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:33', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '96e363e2-0b5b-476d-b883-bfdda86e3a85'	System	15 Aug 2020 05:24:46
User entered 'No (N)'	System	15 Aug 2020 05:24:46

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:37', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '96e363e2-0b5b-476d-b883-bfdda86e3a85'	System	15 Aug 2020 05:24:46
User entered 'No (N)'	System	15 Aug 2020 05:24:46



US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:40', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '96e363e2-0b5b-476d-b883-bfdda86e3a85'	System	15 Aug 2020 05:24:46
User entered 'None (1)'	System	15 Aug 2020 05:24:46

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:43', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '96e363e2-0b5b-476d-b883-bfdda86e3a85'	System	15 Aug 2020 05:24:46
User entered '15 Aug 2020 00:24'	System	15 Aug 2020 05:24:46

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:23', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3c9191e1-51c8-4e7d-ba29-63fb07ffe320' User entered 'None (0)'	System	08 Aug 2020 21:09:53
	System	08 Aug 2020 21:09:53

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:27', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3c9191e1-51c8-4e7d-ba29-63fb07ffe320' User entered 'None (0)'	System	08 Aug 2020 21:09:53
	System	08 Aug 2020 21:09:53

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:30', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3c9191e1-51c8-4e7d-ba29-63fb07ffe320' User entered 'None (0)'	System	08 Aug 2020 21:09:53
	System	08 Aug 2020 21:09:53



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:39', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3c9191e1-51c8-4e7d-ba29-63fb07ffe320' User entered 'None (0)'	System	08 Aug 2020 21:09:53
	System	08 Aug 2020 21:09:53

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:42', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3c9191e1-51c8-4e7d-ba29-63fb07ffe320' User entered 'None (0)'	System	08 Aug 2020 21:09:53
	System	08 Aug 2020 21:09:53

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:44', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3c9191e1-51c8-4e7d-ba29-63fb07ffe320'	System	08 Aug 2020 21:09:53
User entered 'None (0)'	System	08 Aug 2020 21:09:53

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:47', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3c9191e1-51c8-4e7d-ba29-63fb07ffe320'	System	08 Aug 2020 21:09:53
User entered 'No (N)'	System	08 Aug 2020 21:09:53

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-08T16:09:51', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3c9191e1-51c8-4e7d-ba29-63fb07ffe320'	System	08 Aug 2020 21:09:53
User entered '08 Aug 2020 16:09'	System	08 Aug 2020 21:09:53

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Aug 2020 15:53'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Aug 2020 18:23'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 20:36:57



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Aug 2020 19:18'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 2'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:49', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12a2aa60-29f1-4d33-b91a-58479f277703'	System	10 Aug 2020 01:50:10
User entered 'None (0)'	System	10 Aug 2020 01:50:10

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:51', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12a2aa60-29f1-4d33-b91a-58479f277703'	System	10 Aug 2020 01:50:10
User entered 'None (0)'	System	10 Aug 2020 01:50:10

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:53', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12a2aa60-29f1-4d33-b91a-58479f277703' User entered 'None (0)'	System	10 Aug 2020 01:50:10
	System	10 Aug 2020 01:50:10

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:55', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12a2aa60-29f1-4d33-b91a-58479f277703' User entered 'None (0)'	System	10 Aug 2020 01:50:10
	System	10 Aug 2020 01:50:10

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:57', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12a2aa60-29f1-4d33-b91a-58479f277703' User entered 'None (0)'	System	10 Aug 2020 01:50:10
	System	10 Aug 2020 01:50:10



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:49:59', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12a2aa60-29f1-4d33-b91a-58479f277703' User entered 'None (0)'	System	10 Aug 2020 01:50:10
	System	10 Aug 2020 01:50:10

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:50:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12a2aa60-29f1-4d33-b91a-58479f277703'	System	10 Aug 2020 01:50:10
User entered 'No (N)'	System	10 Aug 2020 01:50:10

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-09T20:50:08', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12a2aa60-29f1-4d33-b91a-58479f277703'	System	10 Aug 2020 01:50:10
User entered '09 Aug 2020 20:50'	System	10 Aug 2020 01:50:10

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 3'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:23', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8ca2d7c9-b9fb-4f7d-9f25-f40293903e2d'	System	11 Aug 2020 02:40:50
User entered 'No interference with activity (1)'	System	11 Aug 2020 02:40:50

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:27', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8ca2d7c9-b9fb-4f7d-9f25-f40293903e2d' User entered 'None (0)'	System	11 Aug 2020 02:40:50
	System	11 Aug 2020 02:40:50



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:30', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8ca2d7c9-b9fb-4f7d-9f25-f40293903e2d' User entered 'None (0)'	System	11 Aug 2020 02:40:50
	System	11 Aug 2020 02:40:50

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:33', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8ca2d7c9-b9fb-4f7d-9f25-f40293903e2d' User entered 'None (0)'	System	11 Aug 2020 02:40:50
	System	11 Aug 2020 02:40:50

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:37', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8ca2d7c9-b9fb-4f7d-9f25-f40293903e2d' User entered 'None (0)'	System	11 Aug 2020 02:40:50
	System	11 Aug 2020 02:40:50

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:39', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8ca2d7c9-b9fb-4f7d-9f25-f40293903e2d' User entered 'None (0)'	System	11 Aug 2020 02:40:50
	System	11 Aug 2020 02:40:50

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:42', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8ca2d7c9-b9fb-4f7d-9f25-f40293903e2d' User entered 'No (N)'	System	11 Aug 2020 02:40:50
	System	11 Aug 2020 02:40:50

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-10T21:40:46', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8ca2d7c9-b9fb-4f7d-9f25-f40293903e2d' User entered '10 Aug 2020 21:40'	System	11 Aug 2020 02:40:50
	System	11 Aug 2020 02:40:50

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 20:36:57



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 4'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:16', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3d44674f-40ef-4788-96f9-3310c8e5fee3'	System	12 Aug 2020 01:09:57
User entered 'No interference with activity (1)'	System	12 Aug 2020 01:09:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:20', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3d44674f-40ef-4788-96f9-3310c8e5fee3'	System	12 Aug 2020 01:09:57
User entered 'Some interference with activity (2)'	System	12 Aug 2020 01:09:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:29', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3d44674f-40ef-4788-96f9-3310c8e5fee3'	System	12 Aug 2020 01:09:57
User entered 'No interference with activity (1)'	System	12 Aug 2020 01:09:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:40', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3d44674f-40ef-4788-96f9-3310c8e5fee3'	System	12 Aug 2020 01:09:57
User entered 'No interference with activity (1)'	System	12 Aug 2020 01:09:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:44', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3d44674f-40ef-4788-96f9-3310c8e5fee3' User entered 'None (0)'	System	12 Aug 2020 01:09:57
	System	12 Aug 2020 01:09:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:46', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3d44674f-40ef-4788-96f9-3310c8e5fee3' User entered 'None (0)'	System	12 Aug 2020 01:09:57
	System	12 Aug 2020 01:09:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:49', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3d44674f-40ef-4788-96f9-3310c8e5fee3' User entered 'No (N)'	System	12 Aug 2020 01:09:57
	System	12 Aug 2020 01:09:57



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-11T20:09:54', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '3d44674f-40ef-4788-96f9-3310c8e5fee3' User entered '11 Aug 2020 20:09'	System	12 Aug 2020 01:09:57
	System	12 Aug 2020 01:09:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 5'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:34:05', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '4ed24444-f82d-4224-b0c9-8f5150455a2d' User entered 'None (0)'	System	13 Aug 2020 04:34:28
	System	13 Aug 2020 04:34:28

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:34:09', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '4ed24444-f82d-4224-b0c9-8f5150455a2d' User entered 'None (0)'	System	13 Aug 2020 04:34:28
	System	13 Aug 2020 04:34:28

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:34:11', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '4ed24444-f82d-4224-b0c9-8f5150455a2d' User entered 'None (0)'	System	13 Aug 2020 04:34:28
	System	13 Aug 2020 04:34:28

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:34:13', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '4ed24444-f82d-4224-b0c9-8f5150455a2d' User entered 'None (0)'	System	13 Aug 2020 04:34:28
	System	13 Aug 2020 04:34:28



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:34:15', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '4ed24444-f82d-4224-b0c9-8f5150455a2d' User entered 'None (0)'	System	13 Aug 2020 04:34:28
	System	13 Aug 2020 04:34:28

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:34:19', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '4ed24444-f82d-4224-b0c9-8f5150455a2d' User entered 'None (0)'	System	13 Aug 2020 04:34:28
	System	13 Aug 2020 04:34:28

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:34:22', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '4ed24444-f82d-4224-b0c9-8f5150455a2d' User entered 'No (N)'	System	13 Aug 2020 04:34:28
	System	13 Aug 2020 04:34:28

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-12T23:34:24', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '4ed24444-f82d-4224-b0c9-8f5150455a2d' User entered '12 Aug 2020 23:34'	System	13 Aug 2020 04:34:28
	System	13 Aug 2020 04:34:28

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 6'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:33:57', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '1e52cd9b-e619-495e-9637-85e620966f6e' User entered 'None (0)'	System	13 Aug 2020 22:34:18
	System	13 Aug 2020 22:34:18



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:34:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '1e52cd9b-e619-495e-9637-85e620966f6e' User entered 'None (0)'	System	13 Aug 2020 22:34:18
	System	13 Aug 2020 22:34:18

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:34:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '1e52cd9b-e619-495e-9637-85e620966f6e' User entered 'None (0)'	System	13 Aug 2020 22:34:18
	System	13 Aug 2020 22:34:18

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:34:05', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '1e52cd9b-e619-495e-9637-85e620966f6e' User entered 'None (0)'	System	13 Aug 2020 22:34:18
	System	13 Aug 2020 22:34:18

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:34:08', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '1e52cd9b-e619-495e-9637-85e620966f6e' User entered 'None (0)'	System	13 Aug 2020 22:34:18
	System	13 Aug 2020 22:34:18

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:34:10', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '1e52cd9b-e619-495e-9637-85e620966f6e' User entered 'None (0)'	System	13 Aug 2020 22:34:18
	System	13 Aug 2020 22:34:18

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:34:13', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '1e52cd9b-e619-495e-9637-85e620966f6e' User entered 'No (N)'	System	13 Aug 2020 22:34:18
	System	13 Aug 2020 22:34:18

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-13T17:34:16', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '1e52cd9b-e619-495e-9637-85e620966f6e' User entered '13 Aug 2020 17:34'	System	13 Aug 2020 22:34:18
	System	13 Aug 2020 22:34:18

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 20:36:57



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 7'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:48', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'db81e638-62ba-46b7-8d64-aba0969940ba' User entered 'None (0)'	System	15 Aug 2020 05:25:12
	System	15 Aug 2020 05:25:12

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:51', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'db81e638-62ba-46b7-8d64-aba0969940ba' User entered 'None (0)'	System	15 Aug 2020 05:25:12
	System	15 Aug 2020 05:25:12

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:55', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'db81e638-62ba-46b7-8d64-aba0969940ba' User entered 'None (0)'	System	15 Aug 2020 05:25:12
	System	15 Aug 2020 05:25:12

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:24:58', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'db81e638-62ba-46b7-8d64-aba0969940ba' User entered 'None (0)'	System	15 Aug 2020 05:25:12
	System	15 Aug 2020 05:25:12

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:25:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'db81e638-62ba-46b7-8d64-aba0969940ba' User entered 'None (0)'	System	15 Aug 2020 05:25:12
	System	15 Aug 2020 05:25:12

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:25:02', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'db81e638-62ba-46b7-8d64-aba0969940ba' User entered 'None (0)'	System	15 Aug 2020 05:25:12
	System	15 Aug 2020 05:25:12



US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:25:06', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'db81e638-62ba-46b7-8d64-aba0969940ba' User entered 'No (N)'	System	15 Aug 2020 05:25:12
	System	15 Aug 2020 05:25:12

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-08-15T00:25:09', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'db81e638-62ba-46b7-8d64-aba0969940ba' User entered '15 Aug 2020 00:25'	System	15 Aug 2020 05:25:12
	System	15 Aug 2020 05:25:12

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 20:36:57

US3592075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:32:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:55:20

US3592075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:32:35
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).	System	25 Aug 2020 18:55:50
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 by data change (Site from System).	System	25 Aug 2020 18:55:50
User entered '16 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 18:55:50
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	25 Aug 2020 18:55:20
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:55:20

US3592075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:32:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Aug 2020 18:55:20

US3592075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:32:35
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:55:20



US3592075

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:55:40

US3592075

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'l'	System	25 Aug 2020 18:55:40

US3592075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:33:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:56:32

US3592075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:33:17
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:56:32

US3592075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:33:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Aug 2020 18:56:32

US3592075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:33:17
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:56:32

US3592075

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:33:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:56:35

**US3592075**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:53:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'l'	System	25 Aug 2020 18:56:35



US3592075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:33:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 16:34:08

US3592075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:33:45
User entered '30 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 16:34:08

US3592075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:33:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Aug 2020 16:34:08

US3592075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:33:45
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 16:34:08

US3592075

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:33:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 16:35:23

US3592075

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'l'	System	31 Aug 2020 16:35:23

US3592075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:34:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 17:29:03

US3592075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 14:35:07
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 12:33:21
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'EDC updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:22:05
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:35:04
User entered '5 Sep 2020'	(b) (4), (b) (6)	05 Sep 2020 17:29:03



US3592075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[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 08:13:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 14:35:07
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:29:03

US3592075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'VISIT2'	System	05 Sep 2020 17:29:03

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:56
User closed query 'All values are inconsistent with source, please review and update all data according to source.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 16:35:45
Query 'All values are inconsistent with source, please review and update all data according to source.' (Site from CRA).	Diandra Henriques (b) (4)	12 Feb 2021 20:00:48
answered with 'correct values have been entered.'	(b) (4)	
User entered '05 Sep 2020' reason for change: Data Entry Error	Diandra Henriques (b) (4)	12 Feb 2021 20:00:27
User opened query 'All values are inconsistent with source, please review and update all data according to source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:37:06
User entered '5 Sep 2020'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:56
User entered '11:53' reason for change: Data Entry Error	Diandra Henriques (b) (4)	12 Feb 2021 20:00:06
User entered '09:23'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '05 Sep 2020 11:53'	System	12 Feb 2021 20:00:27
User entered '5 Sep 2020 11:53'	System	12 Feb 2021 20:00:06
User entered '5 Sep 2020 09:23'	System	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:56
User entered '98.9' F reason for change: Data Entry Error	Diandra Henriques (b) (4)	12 Feb 2021 20:00:06
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:30:36



US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:56
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:56
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:56
User entered '76' reason for change: Data Entry Error	Diandra Henriques (b) (4)	12 Feb 2021 20:00:06
User entered '66'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'bpm'	System	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:56
User entered '16'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'breaths/min'	System	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:56
User entered '140' reason for change: Data Entry Error	Diandra Henriques (b) (4)	12 Feb 2021 20:00:06
User entered '102'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'mmHg'	System	05 Sep 2020 17:30:36



US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:56
User entered '88' reason for change: Data Entry Error	Diandra Henriques (b) (4)	12 Feb 2021 20:00:06
User entered '72'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 17:30:36

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'mmHg'	System	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:37:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:37:52
User entered '5 Sep 2020'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:37:54
User entered '12:55' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 21:48:22
User entered '10:38'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '5 Sep 2020 12:55'	System	30 Sep 2020 21:48:22
User entered '5 Sep 2020 10:38'	System	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:37:57
User entered '99.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 21:48:22
User entered '98.1' F	(b) (4), (b) (6)	05 Sep 2020 17:30:36



US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:37:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:00
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:02
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 21:48:22
User entered '63'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'bpm'	System	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:04
User entered '16'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'breaths/min'	System	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:06
User entered '133' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 21:48:22
User entered '105'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'mmHg'	System	05 Sep 2020 17:30:36



US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:08
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).	System	30 Sep 2020 21:48:22
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 by data change (Site from System).	System	30 Sep 2020 21:48:22
User entered '83' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 21:48:22
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 23:49:02
User entered '54'	(b) (4), (b) (6)	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'mmHg'	System	05 Sep 2020 17:30:36

US3592075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 17:29:09

US3592075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:19
User entered '5 Sep 2020'	(b) (4), (b) (6)	05 Sep 2020 17:29:09

US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 17:25:13

US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:41
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 17:25:13

US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

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 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:41
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 17:25:13

US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'MRNA-1273 OR PLACEBO'	System	05 Sep 2020 17:25:13



US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:41
User entered '5 Sep 2020'	(b) (4), (b) (6)	05 Sep 2020 17:25:13

US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:41
User entered '12:23'	(b) (4), (b) (6)	05 Sep 2020 17:25:13

US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '5 Sep 2020 12:23'	System	05 Sep 2020 17:25:13

US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:41
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	05 Sep 2020 17:25:13

US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:38:41
User entered 'ONCE'	System	05 Sep 2020 17:25:13

US3592075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'INTRAMUSCULAR'	System	05 Sep 2020 17:25:13

US3592075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:54:22

US3592075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:47
User entered '5 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 21:54:22



US3592075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:47
User entered '12:15'	(b) (4), (b) (6)	20 Oct 2020 21:54:22

US3592075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '5 Sep 2020 12:15'	System	20 Oct 2020 21:54:22

US3592075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:52
User entered '5 Sep 2020'	(b) (4), (b) (6)	06 Sep 2020 16:39:32

US3592075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Sep 2020 16:39:32

US3592075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Sep 2020 16:39:32

US3592075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:52
User entered '12:00'	(b) (4), (b) (6)	06 Sep 2020 16:39:32

US3592075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '5 Sep 2020 12:00'	System	06 Sep 2020 16:39:32

US3592075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Sep 2020 16:39:32



US3592075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:52
User entered 'No (N)'	(b) (4), (b) (6)	06 Sep 2020 16:39:32

US3592075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:52
User entered empty.	(b) (4), (b) (6)	06 Sep 2020 16:39:32

US3592075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered empty.	System	06 Sep 2020 16:39:32

US3592075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:38:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 17:27:39

US3592075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'I'	System	05 Sep 2020 17:27:39

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:55:59', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9bf0f650-0ddc-4eca-bfc5-fe6a15817bb5' User entered 'Yes (Y)'	System	05 Sep 2020 17:56:13
	System	05 Sep 2020 17:56:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:04', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9bf0f650-0ddc-4eca-bfc5-fe6a15817bb5' User entered '99.1'	System	05 Sep 2020 17:56:13
	System	05 Sep 2020 17:56:13



US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:07', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9bf0f650-0ddc-4eca-bfc5-fe6a15817bb5'	System	05 Sep 2020 17:56:13
User entered 'No (N)'	System	05 Sep 2020 17:56:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:11', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9bf0f650-0ddc-4eca-bfc5-fe6a15817bb5'	System	05 Sep 2020 17:56:13
User entered '05 Sep 2020 12:56'	System	05 Sep 2020 17:56:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '05 Sep 2020 12:43'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '05 Sep 2020 15:13'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26



US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '05 Sep 2020 16:08'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 2'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:35:24', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5382efb9-b315-43fb-83f8-ca077f414702'	System	06 Sep 2020 22:35:53
User entered 'Yes (Y)'	System	06 Sep 2020 22:35:53

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:35:32', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5382efb9-b315-43fb-83f8-ca077f414702' User entered '97.9'	System	06 Sep 2020 22:35:53
	System	06 Sep 2020 22:35:53



US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:35:37', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5382efb9-b315-43fb-83f8-ca077f414702'	System	06 Sep 2020 22:35:53
User entered 'Yes (Y)'	System	06 Sep 2020 22:35:53

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirm subject took Tylenol' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 03:57:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirm subject took Tylenol' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 16:54:31
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Sep 2020 22:35:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:35:46', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5382efb9-b315-43fb-83f8-ca077f414702'	System	06 Sep 2020 22:35:53
User entered '1'	System	06 Sep 2020 22:35:53

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:35:46', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5382efb9-b315-43fb-83f8-ca077f414702'	System	06 Sep 2020 22:35:53
User entered '0'	System	06 Sep 2020 22:35:53

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:35:51', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '5382efb9-b315-43fb-83f8-ca077f414702'	System	06 Sep 2020 22:35:53
User entered '06 Sep 2020 17:35'	System	06 Sep 2020 22:35:53

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 3'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd394dde1-5d2b-4e1c-aba5-7ab4f32c3518' User entered 'Yes (Y)'	System	07 Sep 2020 23:10:41
	System	07 Sep 2020 23:10:41



US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:30', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd394dde1-5d2b-4e1c-aba5-7ab4f32c3518' User entered '96.7'	System	07 Sep 2020 23:10:41
	System	07 Sep 2020 23:10:41

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:33', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd394dde1-5d2b-4e1c-aba5-7ab4f32c3518'	System	07 Sep 2020 23:10:41
User entered 'No (N)'	System	07 Sep 2020 23:10:41

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:36', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd394dde1-5d2b-4e1c-aba5-7ab4f32c3518' User entered '07 Sep 2020 18:10'	System	07 Sep 2020 23:10:41
	System	07 Sep 2020 23:10:41

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 4'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:00:43', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6e770985-1f5d-4c28-a5f3-dcabfb986a22'	System	08 Sep 2020 17:01:47
User entered 'Yes (Y)'	System	08 Sep 2020 17:01:47

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:00:47', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6e770985-1f5d-4c28-a5f3-dcabfb986a22' User entered '97.6'	System	08 Sep 2020 17:01:47
	System	08 Sep 2020 17:01:47



US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:00:51', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6e770985-1f5d-4c28-a5f3-dcabfb986a22'	System	08 Sep 2020 17:01:47
User entered 'Yes (Y)'	System	08 Sep 2020 17:01:47

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirm subject took Tylenol' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 03:57:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirm subject took Tylenol' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 16:54:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 17:01:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:00:55', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6e770985-1f5d-4c28-a5f3-dcabfb986a22'	System	08 Sep 2020 17:01:47
User entered '1'	System	08 Sep 2020 17:01:47

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:00:55', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6e770985-1f5d-4c28-a5f3-dcabfb986a22'	System	08 Sep 2020 17:01:47
User entered '0'	System	08 Sep 2020 17:01:47

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:00:59', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6e770985-1f5d-4c28-a5f3-dcabfb986a22'	System	08 Sep 2020 17:01:47
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 17:01:47

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 5'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:00:40', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b09023cd-f971-434f-8d21-347feca0f473' User entered 'Yes (Y)'	System	09 Sep 2020 21:01:07
	System	09 Sep 2020 21:01:07



US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:00:53', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b09023cd-f971-434f-8d21-347feca0f473' User entered '97.7'	System	09 Sep 2020 21:01:07
	System	09 Sep 2020 21:01:07

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:00:56', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b09023cd-f971-434f-8d21-347feca0f473'	System	09 Sep 2020 21:01:07
User entered 'No (N)'	System	09 Sep 2020 21:01:07

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:00:58', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b09023cd-f971-434f-8d21-347feca0f473' User entered '09 Sep 2020 16:00'	System	09 Sep 2020 21:01:07
	System	09 Sep 2020 21:01:07

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 6'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:35:16', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '88176d0d-53f7-4199-b2a3-44fc2819a96a' User entered 'Yes (Y)'	System	11 Sep 2020 14:35:31
	System	11 Sep 2020 14:35:31

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:35:23', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '88176d0d-53f7-4199-b2a3-44fc2819a96a' User entered '98.0'	System	11 Sep 2020 14:35:31
	System	11 Sep 2020 14:35:31



US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:35:26', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '88176d0d-53f7-4199-b2a3-44fc2819a96a'	System	11 Sep 2020 14:35:31
User entered 'No (N)'	System	11 Sep 2020 14:35:31

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:35:28', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '88176d0d-53f7-4199-b2a3-44fc2819a96a'	System	11 Sep 2020 14:35:31
User entered '11 Sep 2020 09:35'	System	11 Sep 2020 14:35:31

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 7'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:19', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '609cd662-ffbf-43d1-8c3a-81e486fed72c' User entered 'Yes (Y)'	System	12 Sep 2020 05:42:37
	System	12 Sep 2020 05:42:37

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:26', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '609cd662-ffbf-43d1-8c3a-81e486fed72c' User entered '97.7'	System	12 Sep 2020 05:42:37
	System	12 Sep 2020 05:42:37

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:29', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '609cd662-ffbf-43d1-8c3a-81e486fed72c' User entered 'No (N)'	System	12 Sep 2020 05:42:37
	System	12 Sep 2020 05:42:37



US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:32', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '609cd662-ffbf-43d1-8c3a-81e486fed72c' User entered '12 Sep 2020 00:42'	System	12 Sep 2020 05:42:37
	System	12 Sep 2020 05:42:37

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:17', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8d5ddbbc-bfb1-4efd-83b5-64c8554f103b'	System	05 Sep 2020 17:56:33
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 17:56:33

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:20', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8d5ddbbc-bfb1-4efd-83b5-64c8554f103b' User entered 'No (N)'	System	05 Sep 2020 17:56:33
	System	05 Sep 2020 17:56:33

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:23', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8d5ddbbc-bfb1-4efd-83b5-64c8554f103b' User entered 'No (N)'	System	05 Sep 2020 17:56:33
	System	05 Sep 2020 17:56:33

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:26', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8d5ddbbc-bfb1-4efd-83b5-64c8554f103b' User entered 'None (1)'	System	05 Sep 2020 17:56:33
	System	05 Sep 2020 17:56:33



US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:30', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8d5ddbbc-bfb1-4efd-83b5-64c8554f103b' User entered '05 Sep 2020 12:56'	System	05 Sep 2020 17:56:33
	System	05 Sep 2020 17:56:33

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '05 Sep 2020 12:43'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '05 Sep 2020 15:13'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26



US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '05 Sep 2020 16:08'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 2'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ddcc455f-c9b4-44e6-a797-295f08c441b3' User entered 'None (1)'	System	06 Sep 2020 22:36:22
	System	06 Sep 2020 22:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:06', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ddcc455f-c9b4-44e6-a797-295f08c441b3' User entered 'No (N)'	System	06 Sep 2020 22:36:22
	System	06 Sep 2020 22:36:22



US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:09', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ddcc455f-c9b4-44e6-a797-295f08c441b3' User entered 'No (N)'	System	06 Sep 2020 22:36:22
	System	06 Sep 2020 22:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:12', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ddcc455f-c9b4-44e6-a797-295f08c441b3' User entered 'None (1)'	System	06 Sep 2020 22:36:22
	System	06 Sep 2020 22:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:17', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ddcc455f-c9b4-44e6-a797-295f08c441b3' User entered '06 Sep 2020 17:36'	System	06 Sep 2020 22:36:22
	System	06 Sep 2020 22:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 3'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:40', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'da120e13-4a21-4025-a03d-edef27b89f53'	System	07 Sep 2020 23:10:55
User entered 'None (1)'	System	07 Sep 2020 23:10:55

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:43', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'da120e13-4a21-4025-a03d-edef27b89f53' User entered 'No (N)'	System	07 Sep 2020 23:10:55
	System	07 Sep 2020 23:10:55



US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:46', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'da120e13-4a21-4025-a03d-edef27b89f53' User entered 'No (N)'	System	07 Sep 2020 23:10:55
	System	07 Sep 2020 23:10:55

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:48', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'da120e13-4a21-4025-a03d-edef27b89f53'	System	07 Sep 2020 23:10:55
User entered 'None (1)'	System	07 Sep 2020 23:10:55

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:51', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'da120e13-4a21-4025-a03d-edef27b89f53' User entered '07 Sep 2020 18:10'	System	07 Sep 2020 23:10:55
	System	07 Sep 2020 23:10:55

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 4'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6da2b50f-cac5-4aa9-9d7c-a45af80a0346'	System	08 Sep 2020 17:02:12
User entered 'None (1)'	System	08 Sep 2020 17:02:12

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:06', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6da2b50f-cac5-4aa9-9d7c-a45af80a0346' User entered 'No (N)'	System	08 Sep 2020 17:02:12
	System	08 Sep 2020 17:02:12



US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:09', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6da2b50f-cac5-4aa9-9d7c-a45af80a0346'	System	08 Sep 2020 17:02:12
User entered 'No (N)'	System	08 Sep 2020 17:02:12

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:11', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6da2b50f-cac5-4aa9-9d7c-a45af80a0346'	System	08 Sep 2020 17:02:12
User entered 'None (1)'	System	08 Sep 2020 17:02:12

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:14', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6da2b50f-cac5-4aa9-9d7c-a45af80a0346' User entered '08 Sep 2020 12:01'	System	08 Sep 2020 17:02:12
	System	08 Sep 2020 17:02:12

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 5'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6383c6c6-5b6b-4f35-9af2-75896d10568b' User entered 'None (1)'	System	09 Sep 2020 21:01:17
	System	09 Sep 2020 21:01:17

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:07', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6383c6c6-5b6b-4f35-9af2-75896d10568b' User entered 'No (N)'	System	09 Sep 2020 21:01:17
	System	09 Sep 2020 21:01:17



US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:09', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6383c6c6-5b6b-4f35-9af2-75896d10568b' User entered 'No (N)'	System	09 Sep 2020 21:01:17
	System	09 Sep 2020 21:01:17

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:12', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6383c6c6-5b6b-4f35-9af2-75896d10568b' User entered 'None (1)'	System	09 Sep 2020 21:01:17
	System	09 Sep 2020 21:01:17

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:15', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6383c6c6-5b6b-4f35-9af2-75896d10568b' User entered '09 Sep 2020 16:01'	System	09 Sep 2020 21:01:17
	System	09 Sep 2020 21:01:17

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 6'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:35:32', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ca05ea66-5924-442c-8f29-0b7941cca544' User entered 'None (1)'	System	11 Sep 2020 14:35:46
	System	11 Sep 2020 14:35:46

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:35:36', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ca05ea66-5924-442c-8f29-0b7941cca544' User entered 'No (N)'	System	11 Sep 2020 14:35:46
	System	11 Sep 2020 14:35:46



US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:35:38', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ca05ea66-5924-442c-8f29-0b7941cca544' User entered 'No (N)'	System	11 Sep 2020 14:35:46
	System	11 Sep 2020 14:35:46

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:35:41', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ca05ea66-5924-442c-8f29-0b7941cca544' User entered 'None (1)'	System	11 Sep 2020 14:35:46
	System	11 Sep 2020 14:35:46

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:35:44', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ca05ea66-5924-442c-8f29-0b7941cca544' User entered '11 Sep 2020 09:35'	System	11 Sep 2020 14:35:46
	System	11 Sep 2020 14:35:46

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 7'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:36', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a9000031-012d-4186-8a3f-a59bd0105d87'	System	12 Sep 2020 05:42:49
User entered 'None (1)'	System	12 Sep 2020 05:42:49

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:40', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a9000031-012d-4186-8a3f-a59bd0105d87'	System	12 Sep 2020 05:42:49
User entered 'No (N)'	System	12 Sep 2020 05:42:49



US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:42', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a9000031-012d-4186-8a3f-a59bd0105d87'	System	12 Sep 2020 05:42:49
User entered 'No (N)'	System	12 Sep 2020 05:42:49

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:44', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a9000031-012d-4186-8a3f-a59bd0105d87'	System	12 Sep 2020 05:42:49
User entered 'None (1)'	System	12 Sep 2020 05:42:49

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:47', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a9000031-012d-4186-8a3f-a59bd0105d87' User entered '12 Sep 2020 00:42'	System	12 Sep 2020 05:42:49
	System	12 Sep 2020 05:42:49

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:37', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a5c3fbb-26ac-47e8-bc94-4af493f9c0e8'	System	05 Sep 2020 17:57:07
User entered 'No interference with activity (1)'	System	05 Sep 2020 17:57:07

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:43', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a5c3fbb-26ac-47e8-bc94-4af493f9c0e8'	System	05 Sep 2020 17:57:07
User entered 'No interference with activity (1)'	System	05 Sep 2020 17:57:07



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:47', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a5c3fbb-26ac-47e8-bc94-4af493f9c0e8' User entered 'None (0)'	System	05 Sep 2020 17:57:07
	System	05 Sep 2020 17:57:07

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:50', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a5c3fbb-26ac-47e8-bc94-4af493f9c0e8' User entered 'None (0)'	System	05 Sep 2020 17:57:07
	System	05 Sep 2020 17:57:07

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:53', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a5c3fbb-26ac-47e8-bc94-4af493f9c0e8' User entered 'None (0)'	System	05 Sep 2020 17:57:07
	System	05 Sep 2020 17:57:07

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:56:57', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a5c3fbb-26ac-47e8-bc94-4af493f9c0e8' User entered 'None (0)'	System	05 Sep 2020 17:57:07
	System	05 Sep 2020 17:57:07

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:57:02', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a5c3fbb-26ac-47e8-bc94-4af493f9c0e8' User entered 'No (N)'	System	05 Sep 2020 17:57:07
	System	05 Sep 2020 17:57:07

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-05T12:57:05', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a5c3fbb-26ac-47e8-bc94-4af493f9c0e8' User entered '05 Sep 2020 12:57'	System	05 Sep 2020 17:57:07
	System	05 Sep 2020 17:57:07

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '05 Sep 2020 12:43'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '05 Sep 2020 15:13'	System	05 Sep 2020 17:25:13



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '05 Sep 2020 16:08'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 2'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:23', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '851d8519-40c1-4170-866d-34a40b49bd35'	System	06 Sep 2020 22:36:49
User entered 'No interference with activity (1)'	System	06 Sep 2020 22:36:49

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:30', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '851d8519-40c1-4170-866d-34a40b49bd35' User entered 'None (0)'	System	06 Sep 2020 22:36:49
	System	06 Sep 2020 22:36:49

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:32', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '851d8519-40c1-4170-866d-34a40b49bd35' User entered 'None (0)'	System	06 Sep 2020 22:36:49
	System	06 Sep 2020 22:36:49

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:35', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '851d8519-40c1-4170-866d-34a40b49bd35' User entered 'None (0)'	System	06 Sep 2020 22:36:49
	System	06 Sep 2020 22:36:49



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:38', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '851d8519-40c1-4170-866d-34a40b49bd35' User entered 'None (0)'	System	06 Sep 2020 22:36:49
	System	06 Sep 2020 22:36:49

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:40', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '851d8519-40c1-4170-866d-34a40b49bd35' User entered 'None (0)'	System	06 Sep 2020 22:36:49
	System	06 Sep 2020 22:36:49

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:44', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '851d8519-40c1-4170-866d-34a40b49bd35' User entered 'No (N)'	System	06 Sep 2020 22:36:49
	System	06 Sep 2020 22:36:49

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-06T17:36:47', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '851d8519-40c1-4170-866d-34a40b49bd35' User entered '06 Sep 2020 17:36'	System	06 Sep 2020 22:36:49
	System	06 Sep 2020 22:36:49

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 3'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:56', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '72472a51-26a5-4e8a-988a-de9f6d2d2a0a'	System	07 Sep 2020 23:11:17
User entered 'No interference with activity (1)'	System	07 Sep 2020 23:11:17



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:10:59', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '72472a51-26a5-4e8a-988a-de9f6d2d2a0a' User entered 'None (0)'	System	07 Sep 2020 23:11:17
	System	07 Sep 2020 23:11:17

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:11:02', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '72472a51-26a5-4e8a-988a-de9f6d2d2a0a' User entered 'None (0)'	System	07 Sep 2020 23:11:17
	System	07 Sep 2020 23:11:17

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:11:04', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '72472a51-26a5-4e8a-988a-de9f6d2d2a0a' User entered 'None (0)'	System	07 Sep 2020 23:11:17
	System	07 Sep 2020 23:11:17

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:11:06', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '72472a51-26a5-4e8a-988a-de9f6d2d2a0a' User entered 'None (0)'	System	07 Sep 2020 23:11:17
	System	07 Sep 2020 23:11:17

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:11:09', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '72472a51-26a5-4e8a-988a-de9f6d2d2a0a' User entered 'None (0)'	System	07 Sep 2020 23:11:17
	System	07 Sep 2020 23:11:17

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:11:12', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '72472a51-26a5-4e8a-988a-de9f6d2d2a0a' User entered 'No (N)'	System	07 Sep 2020 23:11:17
	System	07 Sep 2020 23:11:17

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-07T18:11:15', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '72472a51-26a5-4e8a-988a-de9f6d2d2a0a' User entered '07 Sep 2020 18:11'	System	07 Sep 2020 23:11:17
	System	07 Sep 2020 23:11:17

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:25:13



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 4'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:20', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c44a747a-282c-4cd3-a2f0-2cccd34b58e9'	System	08 Sep 2020 17:02:56
User entered 'No interference with activity (1)'	System	08 Sep 2020 17:02:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:24', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c44a747a-282c-4cd3-a2f0-2cccd34b58e9' User entered 'None (0)'	System	08 Sep 2020 17:02:56
	System	08 Sep 2020 17:02:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:27', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c44a747a-282c-4cd3-a2f0-2cccd34b58e9' User entered 'None (0)'	System	08 Sep 2020 17:02:56
	System	08 Sep 2020 17:02:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:29', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c44a747a-282c-4cd3-a2f0-2cccd34b58e9' User entered 'None (0)'	System	08 Sep 2020 17:02:56
	System	08 Sep 2020 17:02:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:31', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c44a747a-282c-4cd3-a2f0-2cccd34b58e9' User entered 'None (0)'	System	08 Sep 2020 17:02:56
	System	08 Sep 2020 17:02:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:33', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c44a747a-282c-4cd3-a2f0-2cccd34b58e9' User entered 'None (0)'	System	08 Sep 2020 17:02:56
	System	08 Sep 2020 17:02:56



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:36', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c44a747a-282c-4cd3-a2f0-2cccd34b58e9' User entered 'No (N)'	System	08 Sep 2020 17:02:56
	System	08 Sep 2020 17:02:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-08T12:01:40', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'c44a747a-282c-4cd3-a2f0-2cccd34b58e9' User entered '08 Sep 2020 12:01'	System	08 Sep 2020 17:02:56
	System	08 Sep 2020 17:02:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 5'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:29', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b44bdb9f-ce3c-4828-90bc-0089c3e6c4d9' User entered 'None (0)'	System	09 Sep 2020 21:01:56
	System	09 Sep 2020 21:01:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:41', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b44bdb9f-ce3c-4828-90bc-0089c3e6c4d9' User entered 'None (0)'	System	09 Sep 2020 21:01:56
	System	09 Sep 2020 21:01:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:43', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b44bdb9f-ce3c-4828-90bc-0089c3e6c4d9' User entered 'None (0)'	System	09 Sep 2020 21:01:56
	System	09 Sep 2020 21:01:56



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:45', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b44bdb9f-ce3c-4828-90bc-0089c3e6c4d9' User entered 'None (0)'	System	09 Sep 2020 21:01:56
	System	09 Sep 2020 21:01:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:47', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b44bdb9f-ce3c-4828-90bc-0089c3e6c4d9' User entered 'None (0)'	System	09 Sep 2020 21:01:56
	System	09 Sep 2020 21:01:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:49', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b44bdb9f-ce3c-4828-90bc-0089c3e6c4d9' User entered 'None (0)'	System	09 Sep 2020 21:01:56
	System	09 Sep 2020 21:01:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:51', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b44bdb9f-ce3c-4828-90bc-0089c3e6c4d9'	System	09 Sep 2020 21:01:56
User entered 'No (N)'	System	09 Sep 2020 21:01:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-09T16:01:54', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b44bdb9f-ce3c-4828-90bc-0089c3e6c4d9' User entered '09 Sep 2020 16:01'	System	09 Sep 2020 21:01:56
	System	09 Sep 2020 21:01:56

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 6'	System	05 Sep 2020 17:25:13



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:35:54', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd319aebd-7287-4010-b59f-faec905fbe2d' User entered 'None (0)'	System	11 Sep 2020 14:36:22
	System	11 Sep 2020 14:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:36:04', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd319aebd-7287-4010-b59f-faec905fbe2d'	System	11 Sep 2020 14:36:22
User entered 'No interference with activity (1)'	System	11 Sep 2020 14:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:36:07', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd319aebd-7287-4010-b59f-faec905fbe2d' User entered 'None (0)'	System	11 Sep 2020 14:36:22
	System	11 Sep 2020 14:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:36:10', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd319aebd-7287-4010-b59f-faec905fbe2d' User entered 'None (0)'	System	11 Sep 2020 14:36:22
	System	11 Sep 2020 14:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:36:12', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd319aebd-7287-4010-b59f-faec905fbe2d' User entered 'None (0)'	System	11 Sep 2020 14:36:22
	System	11 Sep 2020 14:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:36:15', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd319aebd-7287-4010-b59f-faec905fbe2d' User entered 'None (0)'	System	11 Sep 2020 14:36:22
	System	11 Sep 2020 14:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:36:18', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd319aebd-7287-4010-b59f-faec905fbe2d' User entered 'No (N)'	System	11 Sep 2020 14:36:22
	System	11 Sep 2020 14:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-11T09:36:20', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'd319aebd-7287-4010-b59f-faec905fbe2d' User entered '11 Sep 2020 09:36'	System	11 Sep 2020 14:36:22
	System	11 Sep 2020 14:36:22



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	05 Sep 2020 17:25:13
User entered 'Day 7'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:54', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a7bb125-87fe-4307-b169-2ee502bf3eea'	System	12 Sep 2020 05:43:11
User entered 'No interference with activity (1)'	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:56', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a7bb125-87fe-4307-b169-2ce502bf3eea' User entered 'None (0)'	System	12 Sep 2020 05:43:11
	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:42:58', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a7bb125-87fe-4307-b169-2ce502bf3eea' User entered 'None (0)'	System	12 Sep 2020 05:43:11
	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:43:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a7bb125-87fe-4307-b169-2ce502bf3eea' User entered 'None (0)'	System	12 Sep 2020 05:43:11
	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:43:02', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a7bb125-87fe-4307-b169-2ce502bf3eea' User entered 'None (0)'	System	12 Sep 2020 05:43:11
	System	12 Sep 2020 05:43:11



US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:43:04', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a7bb125-87fe-4307-b169-2ce502bf3eea' User entered 'None (0)'	System	12 Sep 2020 05:43:11
	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:43:07', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a7bb125-87fe-4307-b169-2ee502bf3eea' User entered 'No (N)'	System	12 Sep 2020 05:43:11
	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-12T00:43:09', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '9a7bb125-87fe-4307-b169-2ee502bf3eea' User entered '12 Sep 2020 00:43'	System	12 Sep 2020 05:43:11
	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 17:25:13

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	12 Sep 2020 05:43:11
User entered 'Day 8'	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-13T00:00:06', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'edba203f-a5fb-405c-b96d-993f7e811edc'	System	13 Sep 2020 05:00:14
User entered 'No interference with activity (1)'	System	13 Sep 2020 05:00:14

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-13T00:00:11', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'edba203f-a5fb-405c-b96d-993f7e811edc' User entered '13 Sep 2020 00:00'	System	13 Sep 2020 05:00:14
	System	13 Sep 2020 05:00:14



US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	12 Sep 2020 05:43:11
User entered 'Day 9'	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-14T02:03:49', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'f8da2694-ac1e-4a19-8026-0b1491f070cc' User entered 'None (0)'	System	14 Sep 2020 07:03:54
	System	14 Sep 2020 07:03:54

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:53:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-14T02:03:53', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'f8da2694-ac1e-4a19-8026-0b1491f070cc' User entered '14 Sep 2020 02:03'	System	14 Sep 2020 07:03:54
	System	14 Sep 2020 07:03:54

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	11 Sep 2020 14:36:22
User entered 'Day 8'	System	11 Sep 2020 14:36:22



US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-13T00:00:17', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'bc096aad-478e-4522-855f-0be3e79363e2' User entered 'No (N)'	System	13 Sep 2020 05:00:25
	System	13 Sep 2020 05:00:25

US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-13T00:00:20', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'bc096aad-478e-4522-855f-0be3e79363e2' User entered '13 Sep 2020 00:00'	System	13 Sep 2020 05:00:25
	System	13 Sep 2020 05:00:25

US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 14:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 14:36:22

US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:53:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	12 Sep 2020 05:43:11
User entered 'Day 9'	System	12 Sep 2020 05:43:11

US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-14T02:03:58', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6b53e07a-30f4-45df-9708-a0beca1865dd' User entered 'No (N)'	System	14 Sep 2020 07:04:02
	System	14 Sep 2020 07:04:02

US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:53:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-09-14T02:04:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6b53e07a-30f4-45df-9708-a0beca1865dd' User entered '14 Sep 2020 02:04'	System	14 Sep 2020 07:04:02
	System	14 Sep 2020 07:04:02

US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:53:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 05:43:11



US3592075

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:53:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 05:43:11

US3592075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:39:41
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	21 Sep 2020 15:02:48
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	21 Sep 2020 15:02:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:02:42

US3592075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:39:41
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:03:28
User entered '13 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:02:48
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:02:42

US3592075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:39:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Sep 2020 15:02:42

US3592075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:39:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:02:42

US3592075

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:39:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:02:55

US3592075

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'l'	System	21 Sep 2020 15:02:55

US3592075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:48:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:40:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:03:10



US3592075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:48:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:40:15
User entered '20 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:03:10

US3592075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:48:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:40:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Sep 2020 15:03:10

US3592075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:48:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:40:15
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:03:10

US3592075

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:48:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:40:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:03:35

US3592075

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'l'	System	21 Sep 2020 15:03:35

US3592075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:40:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:39:18

US3592075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:40:48
User entered '26 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:39:18

US3592075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:40:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Sep 2020 21:39:18



US3592075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:40:48
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:39:18

US3592075

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:40:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:39:22

US3592075

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'l'	System	30 Sep 2020 21:39:22

US3592075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 13:35:38

US3592075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:19
User entered '7 Oct 2020'	(b) (4), (b) (6)	10 Oct 2020 13:35:38

US3592075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[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 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Oct 2020 13:35:38

US3592075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'VISIT3'	System	10 Oct 2020 13:35:38

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 13:36:19



US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:45
User entered '7 Oct 2020'	(b) (4), (b) (6)	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:45
User entered '13:22'	(b) (4), (b) (6)	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '7 Oct 2020 13:22'	System	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:45
User entered '99.5' F	(b) (4), (b) (6)	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:45
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:45
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:45
User entered '85'	(b) (4), (b) (6)	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'bpm'	System	10 Oct 2020 13:36:19



US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:45
User entered '16'	(b) (4), (b) (6)	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'breaths/min'	System	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:45
User entered '119'	(b) (4), (b) (6)	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'mmHg'	System	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:45
User entered '74'	(b) (4), (b) (6)	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'mmHg'	System	10 Oct 2020 13:36:19

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43

US3592075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43



US3592075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Oct 2020 13:36:36

US3592075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:50
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 13:36:36

US3592075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 13:36:53

US3592075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:54
User entered '7 Oct 2020'	(b) (4), (b) (6)	10 Oct 2020 13:36:53

US3592075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:54
User entered '13:38'	(b) (4), (b) (6)	10 Oct 2020 13:36:53

US3592075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered '7 Oct 2020 13:38'	System	10 Oct 2020 13:36:53

US3592075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:07:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:41:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 13:36:58

US3592075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'I'	System	10 Oct 2020 13:36:58



US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 64'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-10T08:59:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b79ca51e-718b-42e8-8ff1-60451baed625'	System	10 Oct 2020 13:59:18
User entered 'No (N)'	System	10 Oct 2020 13:59:18

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-10T08:59:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b79ca51e-718b-42e8-8ff1-60451baed625'	System	10 Oct 2020 13:59:18
User entered 'No (N)'	System	10 Oct 2020 13:59:18

**US3592075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-10T08:59:15', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b79ca51e-718b-42e8-8ff1-60451baed625' User entered '10 Oct 2020 08:59:15'	System	10 Oct 2020 13:59:18
	System	10 Oct 2020 13:59:18

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 71'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-17T22:13:13', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '01cbdf66-64fb-4eb9-b604-1b28a2baa2ff'	System	18 Oct 2020 03:13:38
User entered 'Yes (Y)'	System	18 Oct 2020 03:13:38



US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-17T22:13:17', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '01cbdf66-64fb-4eb9-b604-1b28a2baa2ff'	System	18 Oct 2020 03:13:38
User entered 'No (N)'	System	18 Oct 2020 03:13:38

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-17T22:13:20', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '01cbdf66-64fb-4eb9-b604-1b28a2baa2ff'	System	18 Oct 2020 03:13:38
User entered 'No (N)'	System	18 Oct 2020 03:13:38

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-17T22:13:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '01cbdf66-64fb-4eb9-b604-1b28a2baa2ff'	System	18 Oct 2020 03:13:38
User entered 'No (N)'	System	18 Oct 2020 03:13:38

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-17T22:13:33', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '01cbdf66-64fb-4eb9-b604-1b28a2baa2ff' User entered '17 Oct 2020 22:13:33'	System	18 Oct 2020 03:13:38
	System	18 Oct 2020 03:13:38

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 78'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-24T13:20:53', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '472cab1f-402a-486f-b6d4-f6170e8c6c46'	System	24 Oct 2020 18:21:05
User entered 'No (N)'	System	24 Oct 2020 18:21:05



US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-24T13:20:56', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '472cab1f-402a-486f-b6d4-f6170e8c6c46'	System	24 Oct 2020 18:21:05
User entered 'No (N)'	System	24 Oct 2020 18:21:05

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-10-24T13:21:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '472cab1f-402a-486f-b6d4-f6170e8c6c46' User entered '24 Oct 2020 13:21:03'	System	24 Oct 2020 18:21:05
	System	24 Oct 2020 18:21:05

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 92'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-07T12:00:16', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'af87b7c0-dbb2-4506-9758-0eac262dc500'	System	07 Nov 2020 18:00:26
User entered 'No (N)'	System	07 Nov 2020 18:00:26

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-07T12:00:19', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'af87b7c0-dbb2-4506-9758-0eac262dc500'	System	07 Nov 2020 18:00:26
User entered 'No (N)'	System	07 Nov 2020 18:00:26

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-07T12:00:22', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'af87b7c0-dbb2-4506-9758-0eac262dc500' User entered '07 Nov 2020 12:00:22'	System	07 Nov 2020 18:00:26
	System	07 Nov 2020 18:00:26



US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 99'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-14T15:02:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b14bcd81-5d7d-4fbd-867f-0a8443bf64ec'	System	14 Nov 2020 21:02:13
User entered 'No (N)'	System	14 Nov 2020 21:02:13

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-14T15:02:06', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b14bcd81-5d7d-4fbd-867f-0a8443bf64ec'	System	14 Nov 2020 21:02:13
User entered 'No (N)'	System	14 Nov 2020 21:02:13

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-14T15:02:11', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'b14bcd81-5d7d-4fbd-867f-0a8443bf64ec' User entered '14 Nov 2020 15:02:11'	System	14 Nov 2020 21:02:13
	System	14 Nov 2020 21:02:13

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:54:26
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 20:36:57



**US3592075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52
Data entry locked.	System	08 Aug 2020 20:36:57
User entered 'Day 106'	System	08 Aug 2020 20:36:57

US3592075

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52



US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52



US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 20:36:57

US3592075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:42:52
Data entry locked.	System	08 Aug 2020 20:36:57
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 20:36:57

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-20T08:42:47', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '948a67d3-00f8-45b5-995d-eb72ef247b16'	System	20 Nov 2020 14:43:01
User entered 'No (N)'	System	20 Nov 2020 14:43:01

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-20T08:42:50', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '948a67d3-00f8-45b5-995d-eb72ef247b16' User entered 'No (N)'	System	20 Nov 2020 14:43:01

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-20T08:42:56', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '948a67d3-00f8-45b5-995d-cb72ef247b16' User entered '20 Nov 2020 08:42:56'	System	20 Nov 2020 14:43:01
	System	20 Nov 2020 14:43:01



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-23T15:46:46', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a17e9654-3038-41c3-87a2-33f77905c53c' User entered 'No (N)'	System	23 Nov 2020 23:47:00
	System	23 Nov 2020 23:47:00

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-23T15:46:52', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a17e9654-3038-41c3-87a2-33f77905c53c' User entered 'No (N)'	System	23 Nov 2020 23:47:00

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-11-23T15:46:56', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a17e9654-3038-41c3-87a2-33f77905c53c' User entered '23 Nov 2020 15:46:56'	System	23 Nov 2020 23:47:00
	System	23 Nov 2020 23:47:00

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-04T12:18:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '477dc7d5-f305-49cf-82a7-2359a69fe849' User entered 'No (N)'	System	04 Dec 2020 18:18:15
	System	04 Dec 2020 18:18:15

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-04T12:18:06', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '477dc7d5-f305-49cf-82a7-2359a69fe849' User entered 'No (N)'	System	04 Dec 2020 18:18:15

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-04T12:18:12', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '477dc7d5-f305-49cf-82a7-2359a69fe849' User entered '04 Dec 2020 12:18:12'	System	04 Dec 2020 18:18:15
	System	04 Dec 2020 18:18:15

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-09T12:00:35', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'e7d10506-6011-4744-adb8-3cea0ea90f96'	System	09 Dec 2020 18:00:45
User entered 'No (N)'	System	09 Dec 2020 18:00:45



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-09T12:00:37', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'e7d10506-6011-4744-adb8-3cea0ea90f96'	System	09 Dec 2020 18:00:45
User entered 'No (N)'	System	09 Dec 2020 18:00:45

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-09T12:00:41', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'e7d10506-6011-4744-adb8-3cea0ea90f96' User entered '09 Dec 2020 12:00:41'	System	09 Dec 2020 18:00:45
	System	09 Dec 2020 18:00:45

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-16T11:03:24', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '08b007dd-ab22-4d79-9f89-7b159d98b076'	System	16 Dec 2020 17:03:40
User entered 'No (N)'	System	16 Dec 2020 17:03:40

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-16T11:03:28', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '08b007dd-ab22-4d79-9f89-7b159d98b076'	System	16 Dec 2020 17:03:40
User entered 'No (N)'	System	16 Dec 2020 17:03:40

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-16T11:03:34', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '08b007dd-ab22-4d79-9f89-7b159d98b076' User entered '16 Dec 2020 11:03:34'	System	16 Dec 2020 17:03:40



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-23T12:36:44', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '56f5a4eb-8a68-4a16-b4cd-0b9d4dfc0d13' User entered 'No (N)'	System	23 Dec 2020 18:36:58
	System	23 Dec 2020 18:36:58

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-23T12:36:47', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '56f5a4eb-8a68-4a16-b4cd-0b9d4dfc0d13'	System	23 Dec 2020 18:36:58
User entered 'No (N)'	System	23 Dec 2020 18:36:58

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-23T12:36:55', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '56f5a4eb-8a68-4a16-b4cd-0b9d4dfc0d13' User entered '23 Dec 2020 12:36:55'	System	23 Dec 2020 18:36:58
	System	23 Dec 2020 18:36:58

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:50:17', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered 'Yes (Y)'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:50:24', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered 'No (N)'	System	28 Dec 2020 18:52:05

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:50:38', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered 'Yes (Y)'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered 'l'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '1'	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '1'	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:25', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '0'	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Please 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:32', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf'	System	28 Dec 2020 18:52:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 18:52:05

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:38', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered 'Yes (Y)'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Please 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:44', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf'	System	28 Dec 2020 18:52:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 18:52:05



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2020-12-28T12:51:53', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cbc904e4-6a64-4d86-8f17-32b6f8a74bdf' User entered '28 Dec 2020 12:51:53'	System	28 Dec 2020 18:52:05
	System	28 Dec 2020 18:52:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-04T00:01:48', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a1778f2c-d66b-412f-a773-b52867ae1ea5'	System	04 Jan 2021 06:02:10
User entered 'Yes (Y)'	System	04 Jan 2021 06:02:10

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-04T00:01:45', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a1778f2c-d66b-412f-a773-b52867ae1ea5'	System	04 Jan 2021 06:02:10
User entered 'No (N)'	System	04 Jan 2021 06:02:10

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-04T00:01:56', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a1778f2c-d66b-412f-a773-b52867ae1ea5'	System	04 Jan 2021 06:02:10
User entered 'No (N)'	System	04 Jan 2021 06:02:10

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-04T00:02:04', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a1778f2c-d66b-412f-a773-b52867ae1ea5'	System	04 Jan 2021 06:02:10
User entered 'No (N)'	System	04 Jan 2021 06:02:10



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-04T00:02:08', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'a1778f2c-d66b-412f-a773-b52867ae1ea5' User entered '04 Jan 2021 00:02:08'	System	04 Jan 2021 06:02:10
	System	04 Jan 2021 06:02:10

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-13T15:55:59', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '93be30fb-7ef4-4996-841f-1fbbd44ea410'	System	13 Jan 2021 21:56:37
User entered 'No (N)'	System	13 Jan 2021 21:56:37

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-13T15:55:49', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '93be30fb-7ef4-4996-841f-1fbbd44ea410'	System	13 Jan 2021 21:56:37
User entered 'No (N)'	System	13 Jan 2021 21:56:37

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-13T15:56:03', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '93be30fb-7ef4-4996-841f-1fbbd44ea410' User entered '13 Jan 2021 15:56:03'	System	13 Jan 2021 21:56:37
	System	13 Jan 2021 21:56:37

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-22T20:25:58', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12d198c6-8bcb-40f8-b825-36f8e219508b' User entered 'No (N)'	System	23 Jan 2021 02:26:56
	System	23 Jan 2021 02:26:56

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-22T20:26:01', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12d198c6-8bcb-40f8-b825-36f8e219508b' User entered 'No (N)'	System	23 Jan 2021 02:26:56
	System	23 Jan 2021 02:26:56

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-22T20:26:06', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '12d198c6-8bcb-40f8-b825-36f8e219508b' User entered '22 Jan 2021 20:26:06'	System	23 Jan 2021 02:26:56
	System	23 Jan 2021 02:26:56

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:42:52



US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-26T13:44:41', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cf9dd9d5-8204-4ffc-89aa-8f999c5b8a73'	System	26 Jan 2021 20:33:12
User entered 'No (N)'	System	26 Jan 2021 20:33:12

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-26T13:44:44', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cf9dd9d5-8204-4ffc-89aa-8f999c5b8a73'	System	26 Jan 2021 20:33:12
User entered 'No (N)'	System	26 Jan 2021 20:33:12

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-01-26T13:44:47', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'cf9dd9d5-8204-4ffc-89aa-8f999c5b8a73' User entered '26 Jan 2021 13:44:47'	System	26 Jan 2021 20:33:12
	System	26 Jan 2021 20:33:12

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-02-03T20:35:31', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '61c4aa89-f2b7-496b-bd01-8b5acf2e0fba' User entered 'No (N)'	System	04 Feb 2021 02:35:47

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-02-03T20:35:39', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '61c4aa89-f2b7-496b-bd01-8b5acf2e0fba' User entered 'No (N)'	System	04 Feb 2021 02:35:47



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-02-03T20:35:44', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '61c4aa89-f2b7-496b-bd01-8b5acf2e0fba' User entered '03 Feb 2021 20:35:44'	System	04 Feb 2021 02:35:47

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-02-17T13:12:16', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '39f9061e-f749-427e-8e4b-0b64965e020b' User entered 'No (N)'	System	17 Feb 2021 19:12:27
	System	17 Feb 2021 19:12:27



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-02-17T13:12:19', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '39f9061e-f749-427e-8e4b-0b64965e020b' User entered 'No (N)'	System	17 Feb 2021 19:12:27
	System	17 Feb 2021 19:12:27

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-02-17T13:12:23', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '39f9061e-f749-427e-8e4b-0b64965e020b' User entered '17 Feb 2021 13:12:23'	System	17 Feb 2021 19:12:27
	System	17 Feb 2021 19:12:27

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-02-22T00:01:45', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '990db32d-c5e5-4e0d-b1ba-ee50ad8c38c5' User entered 'No (N)'	System	22 Feb 2021 06:02:00
	System	22 Feb 2021 06:02:00

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-02-22T00:01:48', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '990db32d-c5e5-4e0d-b1ba-ee50ad8c38c5' User entered 'No (N)'	System	22 Feb 2021 06:02:00

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-02-22T00:01:56', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '990db32d-c5e5-4e0d-b1ba-ee50ad8c38c5' User entered '22 Feb 2021 00:01:56'	System	22 Feb 2021 06:02:00
	System	22 Feb 2021 06:02:00



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-01T14:03:43-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'fa39141a-1d55-4a24-9bb7-ee034f3904be' User entered 'No (N)'	System	01 Mar 2021 20:04:55
	System	01 Mar 2021 20:04:55

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-01T14:03:46-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'fa39141a-1d55-4a24-9bb7-ee034f3904be'	System	01 Mar 2021 20:04:55
User entered 'No (N)'	System	01 Mar 2021 20:04:55

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-01T14:03:54-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'fa39141a-1d55-4a24-9bb7-ee034f3904be' User entered '01 Mar 2021 14:03:54'	System	01 Mar 2021 20:04:55
	System	01 Mar 2021 20:04:55

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:42:52

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-11T17:27:34-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '733b9687-fb98-4410-b9d4-3d05c1b2df05'	System	11 Mar 2021 23:27:45
User entered 'No (N)'	System	11 Mar 2021 23:27:45

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-11T17:27:37-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '733b9687-fb98-4410-b9d4-3d05c1b2df05'	System	11 Mar 2021 23:27:45
User entered 'No (N)'	System	11 Mar 2021 23:27:45

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-11T17:27:40-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '733b9687-fb98-4410-b9d4-3d05c1b2df05'	System	11 Mar 2021 23:27:45
User entered '11 Mar 2021 17:27:40'	System	11 Mar 2021 23:27:45

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-19T10:21:54-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'fe6abb7f-f9db-47ac-861d-b05700455df6'	System	19 Mar 2021 16:22:05
User entered 'No (N)'	System	19 Mar 2021 16:22:05



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-19T10:21:57-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'fe6abb7f-f9db-47ac-861d-b05700455df6'	System	19 Mar 2021 16:22:05
User entered 'No (N)'	System	19 Mar 2021 16:22:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-19T10:22:00-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'fe6abb7f-f9db-47ac-861d-b05700455df6'	System	19 Mar 2021 16:22:05
User entered '19 Mar 2021 10:22:00'	System	19 Mar 2021 16:22:05

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-24T12:00:22-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'e45e8072-0b3e-4cb0-b309-9dd6829d8211'	System	24 Mar 2021 17:00:53
User entered 'No (N)'	System	24 Mar 2021 17:00:53

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-24T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'e45e8072-0b3e-4cb0-b309-9dd6829d8211'	System	24 Mar 2021 17:00:53
User entered 'No (N)'	System	24 Mar 2021 17:00:53

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-24T12:00:33-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'e45e8072-0b3e-4cb0-b309-9dd6829d8211' User entered '24 Mar 2021 12:00:33'	System	24 Mar 2021 17:00:53



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-02T16:03:24-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ea614adb-d66d-4aeb-8353-96e1aabab08a' User entered 'No (N)'	System	02 Apr 2021 21:03:41

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-02T16:03:28-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ea614adb-d66d-4aeb-8353-96e1aabab08a' User entered 'No (N)'	System	02 Apr 2021 21:03:41

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-02T16:03:34-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ea614adb-d66d-4aeb-8353-96e1aabab08a' User entered '02 Apr 2021 16:03:34'	System	02 Apr 2021 21:03:41
	System	02 Apr 2021 21:03:41

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:42:52

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-09T13:04:44-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6739afad-4658-4ac9-baf7-710607f4071e'	System	09 Apr 2021 18:05:17
User entered 'Yes (Y)'	System	09 Apr 2021 18:05:17

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-09T13:04:48-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6739afad-4658-4ac9-baf7-710607f4071e'	System	09 Apr 2021 18:05:17
User entered 'No (N)'	System	09 Apr 2021 18:05:17

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-09T13:04:52-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6739afad-4658-4ac9-baf7-710607f4071e' User entered 'No (N)'	System	09 Apr 2021 18:05:17

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-09T13:05:00-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6739afad-4658-4ac9-baf7-710607f4071e' User entered 'No (N)'	System	09 Apr 2021 18:05:17

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-09T13:05:10-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '6739afad-4658-4ac9-baf7-710607f4071e' User entered '09 Apr 2021 13:05:10'	System	09 Apr 2021 18:05:17
	System	09 Apr 2021 18:05:17

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-14T12:00:14-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'f44bd79f-af53-47ed-8c38-a662d68fa004' User entered 'No (N)'	System	14 Apr 2021 17:00:26
	System	14 Apr 2021 17:00:26

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-14T12:00:17-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'f44bd79f-af53-47ed-8c38-a662d68fa004' User entered 'No (N)'	System	14 Apr 2021 17:00:26

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-14T12:00:21-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'f44bd79f-af53-47ed-8c38-a662d68fa004' User entered '14 Apr 2021 12:00:21'	System	14 Apr 2021 17:00:26
	System	14 Apr 2021 17:00:26

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:42:52

US3592075

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-21T14:21:29-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ce1e1e0c-7b02-44af-87eb-940c9565db92'	System	21 Apr 2021 19:22:32
User entered 'Yes (Y)'	System	21 Apr 2021 19:22:32



US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

Have you been exposed to someone with 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-21T14:21:35-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ce1e1e0c-7b02-44af-87eb-940c9565db92' User entered 'No (N)'	System	21 Apr 2021 19:22:32
	System	21 Apr 2021 19:22:32

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

[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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-21T14:21:40-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ce1e1e0c-7b02-44af-87eb-940c9565db92' User entered 'No (N)'	System	21 Apr 2021 19:22:32
	System	21 Apr 2021 19:22:32

US3592075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:27

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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-21T14:21:49-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ce1e1e0c-7b02-44af-87eb-940c9565db92' User entered 'Yes (Y)'	System	21 Apr 2021 19:22:32
	System	21 Apr 2021 19:22:32

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Please 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 (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-21T14:21:57-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ce1e1e0c-7b02-44af-87eb-940c9565db92'	System	21 Apr 2021 19:22:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Apr 2021 19:22:32

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-04-21T14:22:18-05:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: 'ce1e1e0c-7b02-44af-87eb-940c9565db92' User entered '21 Apr 2021 14:22:18'	System	21 Apr 2021 19:22:32
	System	21 Apr 2021 19:22:32

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:42:52

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:42:52



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:42:52

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:42:52



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:42:52



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:42:52

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:42:52

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:42:52



**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:42:52

**US3592075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:53:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:42:52
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:42:52

US3592075

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:53:27**

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)	24 Apr 2021 18:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-03T13:40:41-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8846f05e-85dc-47e7-b4fb-b98071798db3'	System	03 Mar 2021 19:40:51
User entered 'No (N)'	System	03 Mar 2021 19:40:51

**US3592075**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DF2FEF7A-F8EB-4DA0-A9DB-4165018DA1B8)', Time: '2021-03-03T13:40:48-06:00', User OID: 'PatientReportedOutcome (US3592075)', ODM File OID: '8846f05e-85dc-47e7-b4fb-b98071798db3'	System	03 Mar 2021 19:40:51
User entered '03 Mar 2021 13:40:48'	System	03 Mar 2021 19:40:51



US3592075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:43:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:42:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 21:25:45

US3592075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:43:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:42:35
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 21:25:45

US3592075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:43:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Oct 2020 21:25:45

US3592075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:43:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:42:35
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 21:25:45

US3592075

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:43:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:42:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 21:26:06

US3592075

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:13:43
User entered 'l'	System	30 Oct 2020 21:26:06

US3592075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:43:06
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	(b) (4), (b) (6)	29 Jan 2021 06:34:28
' (Site from DM). Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	(b) (4), (b) (6)	25 Jan 2021 20:28:04
' answered with 'illness visit completed ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	(b) (4), (b) (6)	05 Jan 2021 12:25:35
' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Dec 2020 20:37:54

US3592075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:43:06
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:21:09
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' answered with 'lab has been updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:29:24
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 19:55:53
User entered '4 Dec 2020'	(b) (4), (b) (6)	05 Dec 2020 20:37:54



US3592075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:43:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Dec 2020 20:37:54

US3592075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:43:06
User entered empty.	(b) (4), (b) (6)	05 Dec 2020 20:37:54

US3592075

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:21:05
User closed query 'Please confirm if Safety Call Day 149 was performed as subject did become positive for COVID during this same time frame.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 16:21:02
Query 'Please confirm if Safety Call Day 149 was performed as subject did become positive for COVID during this same time frame.' answered with 'SC Day 149 was not performed due to subject being in Convalescent period.' (Site from CRA).	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 20:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 20:46:04
User opened query 'Please confirm if Safety Call Day 149 was performed as subject did become positive for COVID during this same time frame.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 20:45:59
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:43:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Dec 2020 20:37:58

US3592075

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User entered 'l'	System	05 Dec 2020 20:37:58

US3592075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	12 Feb 2021 20:02:35

US3592075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered empty.	(b) (4) Diandra Henriques (b) (4)	12 Feb 2021 20:02:35

US3592075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered empty.	(b) (4) Diandra Henriques (b) (4)	12 Feb 2021 20:02:35

US3592075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Subject was in Convalescent period during this SC Window.'	(b) (4) Diandra Henriques (b) (4)	12 Feb 2021 20:02:35



US3592075

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:53:15

US3592075

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User entered 'l'	System	04 Feb 2021 21:53:15

US3592075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:46:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:53:29

US3592075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:46:12
User entered '2 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:53:29

US3592075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:46:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Feb 2021 21:53:29

US3592075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:46:12
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 21:53:29

US3592075

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:46:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:53:33

US3592075

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:45:15
User entered 'l'	System	04 Feb 2021 21:53:33



US3592075

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:32

US3592075

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:32

US3592075

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[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 07:08:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:32

US3592075

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User entered 'VISIT4'	System	05 Mar 2021 21:47:32

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'Yes (Y)'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '03 Mar 2021'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '13:10'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User entered '03 Mar 2021 13:10'	System	06 Apr 2021 20:45:47



US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '36.7' C	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'Oral (Oral)'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered empty.	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '75'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User entered 'bpm'	System	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '16'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User entered 'breaths/min'	System	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '136'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:45:47



US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User entered 'mmHg'	System	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '81'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User entered 'mmHg'	System	06 Apr 2021 20:45:47

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30

US3592075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30

US3592075

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:40

US3592075

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:40

US3592075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:56



US3592075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:56

US3592075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '13:26'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:56

US3592075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User entered '3 Mar 2021 13:26'	System	05 Mar 2021 21:47:56

US3592075

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:48:00

US3592075

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:30
User entered 'l'	System	05 Mar 2021 21:48:00

US3592075

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:20:40

US3592075

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '2 Apr 2021'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:20:40

US3592075

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:20:40



US3592075

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered empty.	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:20:40

US3592075

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:20:45

**US3592075**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:53:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Apr 2021 16:20:45

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:27

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:58:26
User entered '28 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:27:58

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:27

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:58:26
User entered '08:05'	(b) (4), (b) (6)	25 Jan 2021 19:27:58

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:27

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:14
User entered '28 Dec 2020 08:05'	System	25 Jan 2021 19:27:58

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:27

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:58:26
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	25 Jan 2021 19:27:58

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:58:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:27:58



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '23 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '24 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:31:39



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '25 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:31:39



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '26 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:31:39



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:31:39



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '27 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '28 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:34:38



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '29 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:34:38



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:34:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:36:40

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '30 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '95' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:37:58
User entered '98'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:36:40

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Jan 2021 19:37:58
User entered '98.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:37:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Jan 2021 19:36:40
User entered '95' (non-conformant).	(b) (4), (b) (6)	25 Jan 2021 19:36:40



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:36:40



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '31 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '97'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '97.6' F	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '1 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:45:17



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:45:36
User entered '97.' (non-conformant).	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:45:36
User entered empty.	System	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '98.5' F	(b) (4), (b) (6)	25 Jan 2021 19:45:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:45:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '2 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '96'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '98.9' F	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:58:09
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '3 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Jan 2021 19:54:04



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User closed query 'Per CDM: Per sponsor review, please verify data entered for Symptom Day "Day 14" as it does not follow sequence in symptoms day. Please update accordingly, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 10:45:21
Query 'Per CDM: Per sponsor review, please verify data entered for Symptom Day "Day 14" as it does not follow sequence in symptoms day. Please update accordingly, else clarify. ' answered with 'dates have been updated ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 20:58:08
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 20:57:19
User opened query 'Per CDM: Per sponsor review, please verify data entered for Symptom Day "Day 14" as it does not follow sequence in symptoms day. Please update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:24:00
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:58:09
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '4 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '91'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '98.1' F	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:57:19
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:58:09
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '5 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '95' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:58:09
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:58:09
User entered empty.	System	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '99.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:58:09
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Form: Symptom Log (14)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:57:19
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:58:09
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '6 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '95' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:58:09
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:58:09
User entered empty.	System	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	25 Jan 2021 19:58:09
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:54:04

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:58:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:54:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:57:19
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '7 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '96'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 19:58:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '98.0' F	(b) (4), (b) (6)	25 Jan 2021 19:58:09



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 19:58:09



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:57:19
User entered 'Day 18 (Day 18)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '8 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '96'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '98.2' F	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:57:19
User entered 'Day 19 (Day 19)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '9 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 20:06:54



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '95'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '98.0' F	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:06:54

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:57:19
User entered 'Day 20 (Day 20)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '10 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:10:19
User entered '11 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '94'	(b) (4), (b) (6)	25 Jan 2021 20:08:48



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '98.4' F	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:08:48

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:57:19
User entered 'Day 21 (Day 21)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '11 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '95'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User entered '%'	System	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered '98.0' F	(b) (4), (b) (6)	25 Jan 2021 20:10:19



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19



US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:53:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:24
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:14
User entered 'None (None)'	(b) (4), (b) (6)	25 Jan 2021 20:10:19



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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:27

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:26
User entered '28 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 20:11:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:27

[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 23:22:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 20:11:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:27

[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 23:22:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:26
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)	28 Jan 2021 03:54:28
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 'page completed ' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 20:11:27
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	25 Jan 2021 20:11:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 20:11:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:27

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:26
User entered '28 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 20:11:17

US3592075

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:27

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:26
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	25 Jan 2021 20:11:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:27

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:26
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:11:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:27

[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 23:22:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:26
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:11:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:26
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:11:17



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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:26
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:11:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:53:27

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:36
User entered 'l'	System	25 Jan 2021 20:11:17

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

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 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38



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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

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 23:22:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:04:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Please verify as symptom log on 04Jan2021 notes O2 that meets severity criteria' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:24:45
Query 'Please verify as symptom log on 04Jan2021 notes O2 that meets severity criteria' answered with 'updated questions and values' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 21:00:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 21:00:01
User opened query 'Please verify as symptom log on 04Jan2021 notes O2 that meets severity criteria' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:16:41
User closed query 'Per CDM: Per sponsor review, Symptom Log Day 14 reports SpO2 < 93%. However, Did the Subject have Oxygen Saturation of SpO2 < 93%? is recorded as No. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 05:01:30
Query 'Per CDM: Per sponsor review, Symptom Log Day 14 reports SpO2 < 93%. However, Did the Subject have Oxygen Saturation of SpO2 < 93%? is recorded as No. Please review and reconcile.' answered with 'question completed' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 17:33:56
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 17:33:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 17:33:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 17:33:47
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 17:33:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 17:33:30
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 17:32:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 17:32:43

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 17:32:43
User opened query 'Data is required. Please complete.' (Site from System). DataPoint Un-verified.	System	08 Mar 2021 17:32:14
	(b) (4), (b) (6)	08 Mar 2021 17:32:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 17:32:14
User opened query 'Per CDM: Per sponsor review, Symptom Log Day 14 reports SpO2 < 93%. However, Did the Subject have Oxygen Saturation of SpO2 < 93%? is recorded as No. Please review and reconcile.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 14:47:38
	(b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:04:38
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Please verify as symptom log on 04Jan2021 shows an O2 that meets this criteria' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:24:43
Query 'Please verify as symptom log on 04Jan2021 shows an O2 that meets this criteria' answered with 'updated date ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 21:00:43
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 21:00:01
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 21:00:01
User opened query 'Please verify as symptom log on 04Jan2021 shows an O2 that meets this criteria' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:17:07
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:04:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Please verify as only one date meets this criteria on symptom log on 04Jan2021' (Site from CRA).	(b) (4)	
Query 'Please verify as only one date meets this criteria on symptom log on 04Jan2021' answered with 'updated date ' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 21:24:42
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 21:00:48
	(b) (4), (b) (6)	18 Mar 2021 21:00:01
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 21:00:01
User opened query 'Please verify as only one date meets this criteria on symptom log on 04Jan2021' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:17:32
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4)	05 Feb 2021 16:21:38
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:04:35
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Please verify as symptom log shows O2 on 04Jan2021 of 91%' (Site from CRA).	(b) (4)	22 Mar 2021 21:24:41
Query 'Please verify as symptom log shows O2 on 04Jan2021 of 91%' answered with 'updated values ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 21:00:56
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 21:00:01
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 21:00:01
User opened query 'Please verify as symptom log shows O2 on 04Jan2021 of 91%' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:17:50
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4)	05 Feb 2021 16:21:38
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:53:27

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:04:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 17:33:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 17:33:30
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 17:32:43
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 17:32:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 17:32:43
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered 'No (N)'	Diandra Henriques (b) (4)	05 Feb 2021 16:21:38
	(b) (4)	



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:47:04
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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:47:04
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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[Start Date](#)

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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 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
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User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
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User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:47:04
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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[ECMO?](#)

Audit	User	Time (GMT)
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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
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[Evidence of Shock Requires](#)

[Vasopressors](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
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Folder: Covid-19 Assessment 28 Dec 2020

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[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 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:46
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:21:38

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:53:27

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:22:55
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:14
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 16:13:09

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:53:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User accepted default value 'Day 3 (Day 3)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40



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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:53:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:53:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered '30 Dec 2020'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:53:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User accepted default value 'Day 5 (Day 5)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:53:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:53:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered empty.	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:53:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User accepted default value 'Day 7 (Day 7)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:53:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

**US3592075**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:53:27**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered empty.	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40



US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:53:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User accepted default value 'Day 9 (Day 9)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:53:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:53:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered '05 Jan 2021'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:53:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User accepted default value 'Day 14 (Day 14)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:53:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:53:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User closed query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 10JAN2021 is reported in PPD central lab with 12JAN2021 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 06:44:38
Query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 10JAN2021 is reported in PPD central lab with 12JAN2021 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'EDC date is accurate. Demo Change request sent to Preclarus to correct' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 19:58:40
User opened query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 10JAN2021 is reported in PPD central lab with 12JAN2021 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 12:31:54
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered '10 Jan 2021'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:53:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User accepted default value 'Day 21 (Day 21)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:53:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40



US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:53:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User closed query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 17JAN2021 is reported in PPD central lab with 21JAN2021 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 06:44:42
Query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 17JAN2021 is reported in PPD central lab with 21JAN2021 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'EDC date is accurate. Demo Change request sent to Preclarus to correct' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 19:58:46
User opened query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 17JAN2021 is reported in PPD central lab with 21JAN2021 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 12:32:47
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered '17 Jan 2021'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:53:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User accepted default value 'Day 28 (Day 28)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:53:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User closed query 'Per GCL LAB reconciliation: Saliva: Illness visit Day 28 sample dated 29JAN2021 is labelled as Unscheduled Visit in PPD. Please review the Preclarus data and confirm the correct visit label for the sample and amend EDC or Preclarus. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 07:14:13
Query 'Per GCL LAB reconciliation: Saliva: Illness visit Day 28 sample dated 29JAN2021 is labelled as Unscheduled Visit in PPD. Please review the Preclarus data and confirm the correct visit label for the sample and amend EDC or Preclarus. Thank you.' answered with 'Unscheduled Kit was used for Illness D28. Demo change request form has been sent to Preclarus to correct.' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 19:43:41
User opened query 'Per GCL LAB reconciliation: Saliva: Illness visit Day 28 sample dated 29JAN2021 is labelled as Unscheduled Visit in PPD. Please review the Preclarus data and confirm the correct visit label for the sample and amend EDC or Preclarus. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 12:33:41
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

US3592075

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:53:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:48:07
User entered '29 Jan 2021'	Diandra Henriques (b) (4) (b) (4)	04 Feb 2021 17:16:40

**US3592075**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:53:27**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:44
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:25:42

US3592075

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:44
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:39
User entered '28 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:25:42

US3592075

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[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 07:20:44
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Jan 2021 19:25:42

US3592075

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:44
User entered 'SICKD1'	System	25 Jan 2021 19:25:42



US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered '28 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered '16:32'	(b) (4), (b) (6)	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User entered '28 Dec 2020 16:32'	System	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered '161.0' cm	(b) (4), (b) (6)	25 Jan 2021 19:26:34
DataPoint set to visible.	System	25 Jan 2021 19:25:42

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered '92.3' kg	(b) (4), (b) (6)	25 Jan 2021 19:26:34
DataPoint set to visible.	System	25 Jan 2021 19:25:42

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered '37.0' C	(b) (4), (b) (6)	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Jan 2021 19:26:34



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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered '86'	(b) (4), (b) (6)	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User entered 'bpm'	System	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered '16'	(b) (4), (b) (6)	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User entered 'breaths/min'	System	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered '153'	(b) (4), (b) (6)	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User entered 'mmHg'	System	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:50
User entered '86'	(b) (4), (b) (6)	25 Jan 2021 19:26:34



US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51
User entered 'mmHg'	System	25 Jan 2021 19:26:34

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51

US3592075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:24:51

US3592075

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:26:42

US3592075

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:15
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:55
User entered '28 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:26:42

US3592075

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:53:27

[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 07:25:23
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:01:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:27:01

US3592075

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:53:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:25:23
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:01:05
User entered '28 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 19:27:01

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:13
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:44:12



US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:13
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:42
User entered '29 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 21:44:12

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[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 12:22:13
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Feb 2021 21:44:12

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:13
User entered 'SICKD28'	System	04 Feb 2021 21:44:12

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered '29 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered '16:45'	(b) (4), (b) (6)	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User entered '29 Jan 2021 16:45'	System	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered '161.0' cm	(b) (4), (b) (6)	04 Feb 2021 21:47:15
DataPoint set to visible.	System	04 Feb 2021 21:44:12



US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered '93.5' kg	(b) (4), (b) (6)	04 Feb 2021 21:47:15
DataPoint set to visible.	System	04 Feb 2021 21:44:12

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered '36.1' C	(b) (4), (b) (6)	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered '88'	(b) (4), (b) (6)	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User entered 'bpm'	System	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered '16'	(b) (4), (b) (6)	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User entered 'breaths/min'	System	04 Feb 2021 21:47:15



US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered '111'	(b) (4), (b) (6)	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User entered 'mmHg'	System	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:46
User entered '70'	(b) (4), (b) (6)	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20
User entered 'mmHg'	System	04 Feb 2021 21:47:15

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:20

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:45:07

US3592075

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:51
User entered '29 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 21:45:07



US3592075

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:53:27

[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 12:22:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:47:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:46:03

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Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:53:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:22:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Per GCL Lab Reconciliation: SARS-CoV2 sample: It appears Sample dated 29 JAN 2021 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 sample is reported under UNSCHEDULED visit in PPD Central Lab. Please confirm the correct Visit Label in the response, and update in Preclarus PPD portal as appropriate so that there is matching of data between EDC & PPD GCL records. Thank you.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 08:26:16
' (Site from DM). Query 'Per GCL Lab Reconciliation: SARS-CoV2 sample: It appears Sample dated 29 JAN 2021 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 sample is reported under UNSCHEDULED visit in PPD Central Lab. Please confirm the correct Visit Label in the response, and update in Preclarus PPD portal as appropriate so that there is matching of data between EDC & PPD GCL records. Thank you.	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 19:39:05
' answered with 'Unscheduled lab kit was used for Illness D28 visit inadvertently. demo change request form has been submitted to Preclarus.' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: SARS-CoV2 sample: It appears Sample dated 29 JAN 2021 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 sample is reported under UNSCHEDULED visit in PPD Central Lab. Please confirm the correct Visit Label in the response, and update in Preclarus PPD portal as appropriate so that there is matching of data between EDC & PPD GCL records. Thank you.	(b) (4), (b) (6)	11 Feb 2021 15:46:32
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:47:55

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:53:27

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '29 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 21:46:03

US3592075

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:49:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:47:40

US3592075

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:49:00
User entered '1 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:47:40

US3592075

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[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 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:49:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Feb 2021 21:47:40

US3592075

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 21:47:40

US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:49:42
User entered '1 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:48:20



US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:30:55

US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:49:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:48:20

US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
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 03:30:55

US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:49:42
User entered '1 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:48:20

US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:49:42
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	04 Feb 2021 21:48:20

US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:49:42
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	04 Feb 2021 21:48:20

US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:49:42
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	04 Feb 2021 21:48:20

US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:49:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:48:20



US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'I'	System	04 Feb 2021 21:48:20

US3592075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:27

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'I'	System	04 Feb 2021 21:48:20

US3592075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '94.4' kg	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered empty.	System	04 Feb 2021 21:51:50
DataPoint set to visible.	System	04 Feb 2021 21:48:20

US3592075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '94.4' kg	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered empty.	System	04 Feb 2021 21:51:50
DataPoint set to visible.	System	04 Feb 2021 21:48:20



US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '1 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '13:32'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered '1 Feb 2021 13:32'	System	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '37.0' C	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 21:51:50



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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '85'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'bpm'	System	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '16'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'breaths/min'	System	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '101'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'mmHg'	System	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '78'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'mmHg'	System	04 Feb 2021 21:51:50



US3592075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '94.4' kg	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered empty.	System	04 Feb 2021 21:51:50
DataPoint set to visible.	System	04 Feb 2021 21:48:20

US3592075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '1 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '14:31'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered '1 Feb 2021 14:31'	System	04 Feb 2021 21:51:50



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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '99.0' F	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 21:51:50

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '71'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'bpm'	System	04 Feb 2021 21:51:50

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '16'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'breaths/min'	System	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '157'	(b) (4), (b) (6)	04 Feb 2021 21:51:50



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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'mmHg'	System	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:50:46
User entered '84'	(b) (4), (b) (6)	04 Feb 2021 21:51:50

US3592075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'mmHg'	System	04 Feb 2021 21:51:50

US3592075

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:48:41

US3592075

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:02
User entered '1 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:48:41

US3592075

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:52:19

US3592075

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:10
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 21:52:19

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:10
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 21:52:19



US3592075

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'mRNA-1273'	System	04 Feb 2021 21:52:19
DataPoint set to visible.	System	04 Feb 2021 21:48:20

US3592075

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:10
User entered '1 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:52:19

US3592075

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:10
User entered '13:59'	(b) (4), (b) (6)	04 Feb 2021 21:52:19

US3592075

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered '1 Feb 2021 13:59'	System	04 Feb 2021 21:52:19

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:10
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	04 Feb 2021 21:52:19

US3592075

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:51:10
User entered 'ONCE'	System	04 Feb 2021 21:52:19

US3592075

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'INTRAMUSCULAR'	System	04 Feb 2021 21:52:19

US3592075

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:52:49



US3592075

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:13
User entered '1 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:52:49

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:13
User entered '13:37'	(b) (4), (b) (6)	04 Feb 2021 21:52:49

US3592075

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered '1 Feb 2021 13:37'	System	04 Feb 2021 21:52:49

US3592075

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:53:01

US3592075

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:18
User entered '1 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:53:01

US3592075

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:18
User entered '13:39'	(b) (4), (b) (6)	04 Feb 2021 21:53:01

**US3592075**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:53:27**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered '1 Feb 2021 13:39'	System	04 Feb 2021 21:53:01

US3592075

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

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:49:47



US3592075

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

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'I'	System	04 Feb 2021 21:49:47

US3592075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 14:47:36

US3592075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:29
User entered '8 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 14:47:36

US3592075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Feb 2021 14:47:36

US3592075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:29
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 14:47:36

US3592075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 14:47:41

US3592075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User entered 'l'	System	09 Feb 2021 14:47:41

US3592075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User entered 'I'	System	09 Feb 2021 14:47:41
DataPoint set to visible.	System	09 Feb 2021 14:47:41



US3592075

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:46:28

**US3592075**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:53:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:46:28

US3592075

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[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 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:46:28

US3592075

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'OLD29'	System	05 Mar 2021 21:46:28

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '13:10'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13



US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered '3 Mar 2021 13:10'	System	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '75'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'bpm'	System	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'breaths/min'	System	05 Mar 2021 21:50:13



US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '136'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'mmHg'	System	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '81'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'mmHg'	System	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '14:22'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13



US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered '3 Mar 2021 14:22'	System	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '70'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'bpm'	System	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'breaths/min'	System	05 Mar 2021 21:50:13



US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '161'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'mmHg'	System	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '90'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'mmHg'	System	05 Mar 2021 21:50:13

US3592075

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:19

US3592075

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:19

US3592075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:46:59

US3592075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:46:59



US3592075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:46:59

US3592075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'mRNA-1273'	System	05 Mar 2021 21:46:59
DataPoint set to visible.	System	09 Feb 2021 14:47:41

US3592075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:46:59

US3592075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '13:50'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:46:59

US3592075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered '3 Mar 2021 13:50'	System	05 Mar 2021 21:46:59

US3592075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:46:59

US3592075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'ONCE'	System	05 Mar 2021 21:46:59

US3592075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 21:46:59



US3592075

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:47:03

US3592075

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'l'	System	05 Mar 2021 21:47:03

**US3592075**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:53:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:17:08

US3592075

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:17:08

US3592075

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:17:08

**US3592075**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:53:27**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:17:08

US3592075

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:17:12

**US3592075**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:53:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:25
User entered 'l'	System	11 Mar 2021 17:17:12



**US3592075**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:53:27**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:21:33

US3592075

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '1 Apr 2021'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:21:33

US3592075

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'Clinic (Clinic)'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:21:33

**US3592075**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:53:27**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	03 Apr 2021 16:21:33

US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:04

US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '1 Apr 2021'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:04

US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '09:22'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:04

**US3592075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:53:27**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Apr 2021 09:22'	System	03 Apr 2021 16:22:04



US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '36.8' C	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:04

US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'Oral (Oral)'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:04

US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered empty.	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:04

US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '87'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:04

**US3592075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:53:27**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Apr 2021 16:22:04

US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '16'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:04

US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Apr 2021 16:22:04

US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '140'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:04



**US3592075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:53:27**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Apr 2021 16:22:04

US3592075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '85'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:04

**US3592075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:53:27**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Apr 2021 16:22:04

US3592075

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'No (N)'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:09

US3592075

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered empty.	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:09

US3592075

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:23

US3592075

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '1 Apr 2021'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:23

US3592075

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User entered '09:27'	(b) (4) (D) (4), (D) (6)	03 Apr 2021 16:22:23



**US3592075**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:53:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Apr 2021 09:27'	System	03 Apr 2021 16:22:23

US3592075

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:53:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:19:42
User closed query 'Per DM CLR RQ: Response noted, However please note that per Diary dose 2, Headache day form, subject reported Headache beyond 7 day post injection on Day 8 i.e. 13 SEP 2020. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 05:58:15
Query 'Per DM CLR RQ: Response noted, However please note that per Diary dose 2, Headache day form, subject reported Headache beyond 7 day post injection on Day 8 i.e. 13 SEP 2020. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated time added ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 17:34:27
User opened query 'Per DM CLR RQ: Response noted, However please note that per Diary dose 2, Headache day form, subject reported Headache beyond 7 day post injection on Day 8 i.e. 13 SEP 2020. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 10:26:03
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary "Headache" lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 10:26:03

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:53:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary "Headache" lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.'	(b) (4), (b) (6)	19 Apr 2021 19:57:11
answered with 'subject reported headache stopping on day 7 9/11/2020. subject did not report headache beyond day 7' (Site from DM).		
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary "Headache" lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 18:23:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:51:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:13:44
User entered 'No (N)'	(b) (4), (b) (6)	05 Sep 2020 17:30:50

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Ocular disorders NEC, PT: Eye swelling, LLT: Eye swelling - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 20:16:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 20:16:54
Data point term sent to Coder	System	25 Jan 2021 20:15:59
User entered 'swollen right eye'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '23 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 20:15:11



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:15:11

**US3592075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:53:27**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:15:11



US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:15:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:15:11



US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'see line #13-line #15' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 01:50:36
	(b) (4), (b) (6)	08 Mar 2021 17:25:48
	(b) (4), (b) (6)	19 Feb 2021 12:09:43
	(b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:15:11



US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:01
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:15:11

US3592075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 20:15:11

**US3592075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 20:15:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:22:28
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:35:48
User entered 'USA-US103-2021-mRNA-1273-P301000003'	System	18 Feb 2021 19:35:34
User entered 'New'	(b) (4), (b) (6)	18 Feb 2021 19:35:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
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)	05 Feb 2021 16:27:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Feb 2021 16:27:51
Data point term sent to Coder	System	05 Feb 2021 16:27:07
Coding entries removed.	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:26:33
User entered 'SYMPTOMATIC COVID-19' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:26:33
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)	25 Jan 2021 20:17:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Jan 2021 20:17:51
Data point term sent to Coder	System	25 Jan 2021 20:16:59
User entered 'COVID-19'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 20:16:19



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

US3592075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Diandra Henriques (b) (4)	05 Feb 2021 16:26:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '23 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

US3592075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:53:27**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered 'No (N)' reason for change: New Information	Diandra Henriques (b) (4)	05 Feb 2021 16:26:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered '11 Jan 2021' reason for change: New Information	Diandra Henriques (b) (4)	05 Feb 2021 16:26:33
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:16:19

**US3592075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:53:27**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:16:19



**US3592075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:53:27**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

US3592075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

US3592075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

US3592075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

US3592075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

US3592075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:16:19



**US3592075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:16:19

US3592075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

US3592075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Jan 2021 20:16:19



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Diandra Henriques (b) (4) (b) (4)	05 Feb 2021 16:26:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:16:19

US3592075

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:53:20
User entered 'SUBJECT REPORTED BEING EXPOSED TO A COVID POSITIVE INDIVIDUAL ON 15 NOV 2020 FOR THE LENGTH OF 3 DAYS. NO OTHER CONFIRMED EXPOSURE AFTER THAT DATE.' reason for change: New Information	Diandra Henriques (b) (4)	05 Feb 2021 16:43:48
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:16:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 20:16:19

**US3592075**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Jan 2021 20:16:19



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 08:22:05
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 20:29:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 20:29:02
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'AE term updated' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 20:28:42
Data point term sent to Coder	System	10 Mar 2021 20:28:35
DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 20:27:55
Coding entries removed.	(b) (4), (b) (6)	10 Mar 2021 20:27:55
User entered 'Worsening of hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 20:27:55
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 17:15:45
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 12:09:54

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:53:20
User coded data point as SOC: Investigations, HLT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 20:18:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 20:18:53
Data point term sent to Coder	System	25 Jan 2021 20:18:01
User entered 'elevated blood pressure'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

US3592075

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

US3592075

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '10 Sep 2020'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

US3592075

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:17:40



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User entered empty.	System	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Jan 2021 20:17:55
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Jan 2021 20:17:55
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Jan 2021 20:17:40
User entered '30 Sep 2020'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User entered empty.	System	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:46:00
User closed query 'Per DM CLR: Please review Severity and please note, worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update as appropriate or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 07:37:48
Query 'Per DM CLR: Please review Severity and please note, worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update as appropriate or provide clarification.' answered with 'CORRECTED GRADING' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	09 Apr 2021 15:05:29
DataPoint Un-verified.	Diandra Henriques (b) (4) (b) (4)	09 Apr 2021 15:05:08
Signature has been broken.	Diandra Henriques (b) (4) (b) (4)	09 Apr 2021 15:05:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	09 Apr 2021 15:05:08
User opened query 'Per DM CLR: Please review Severity and please note, worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 15:15:27
User signature succeeded.	Terry Poling (b) (4) (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:53:20
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 20:17:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 20:17:55
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:17:55
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 20:17:40
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:17:40



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

US3592075

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:17:40



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'l'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:17:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	25 Jan 2021 20:17:40



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

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 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User entered '0'	System	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42
User entered '0'	System	25 Jan 2021 20:17:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:53:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52

US3592075

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 19:05:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 19:05:06
Data point term sent to Coder	System	21 Apr 2021 17:35:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Apr 2021 17:34:44
Data point term sent to Coder	System	08 Mar 2021 17:31:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 21:28:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 21:28:42
Data point term sent to Coder	System	15 Feb 2021 21:28:05
User entered 'headache'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'No (N)'	(b) (4), (b) (6)	15 Feb 2021 21:27:19



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'No (N)'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered '5 Sep 2020'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
User closed query 'Per CDM: Per CCG's if start time is within 24 hrs from IP dose, start time is required. Please enter the estimated time fo rthis AE.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 05:58:57
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:34:55
User entered '17:00' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 17:34:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
Query 'Per CDM: Per CCG's if start time is within 24 hrs from IP dose, start time is required. Please enter the estimated time fo rthis AE.' answered with 'AE deleted since captured in diary ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 17:30:42
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User opened query 'Per CDM: Per CCG's if start time is within 24 hrs from IP dose, start time is required. Please enter the estimated time fo rthis AE.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 06:57:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Feb 2021 06:56:07
Query 'Data is required. Please provide.' answered with 'TIME IS UNKNOWN ' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 21:27:41
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Feb 2021 21:27:19
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User entered '5 Sep 2020 17:00'	System	21 Apr 2021 17:34:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
User entered empty.	System	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'No (N)'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 17:29:47
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 17:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered '11 Feb 2021'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Feb 2021 06:56:09
Query 'Data is required. Please provide.' answered with 'TIME IS UNKNOWN' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 21:27:52
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Feb 2021 21:27:19
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 21:27:19



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Generated On: 11 Aug 2021 22:53:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
User entered empty.	System	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'No (N)'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered '0'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered '0'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered '0'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:53:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:53:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 21:27:19



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered '0'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered '0'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered '0'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Feb 2021 21:27:19



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered '0'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'l'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered '0'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

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Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	15 Feb 2021 21:27:19

US3592075

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

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 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 21:27:19

US3592075

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:10:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:28
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 21:27:19

US3592075

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
User entered '0'	System	15 Feb 2021 21:27:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52
User entered '0'	System	15 Feb 2021 21:27:19



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:53:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:23:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Apr 2021 17:34:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Mar 2021 17:30:52

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:53:27**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:19:42
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:53:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:49:07

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: PAROXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:51:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:51:12
Data point term sent to Coder	System	11 Aug 2020 14:50:45
User entered 'Paroxetine'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Depression'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '40'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:50:19



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:50:19

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:50:19

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
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)	13 Aug 2020 03:44:17
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 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:50:34
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	11 Aug 2020 14:50:19
User entered 'un UNK 2005'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:50:19



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:50:19

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Aug 2020 14:50:19

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Aug 2020 14:50:19

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 14:50:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:53:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:53:37
Data point term sent to Coder	System	11 Aug 2020 14:52:48
User entered 'Metformin'	(b) (4), (b) (6)	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'Hyperglycemia'	(b) (4), (b) (6)	11 Aug 2020 14:52:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '500'	(b) (4), (b) (6)	11 Aug 2020 14:52:09



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 14:52:09

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:52:09

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:52:09

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
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)	13 Aug 2020 03:44:28
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 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:52:15
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	11 Aug 2020 14:52:09
User entered 'un UNK 2006'	(b) (4), (b) (6)	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:52:09



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Aug 2020 14:52:09

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 14:52:09

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:55:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:55:16
Data point term sent to Coder User entered 'Diltiazem'	System (b) (4), (b) (6)	11 Aug 2020 14:53:49 11 Aug 2020 14:52:55

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:52:55



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Hypertension'	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '90'	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:52:55



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
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)	13 Aug 2020 03:44:36
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 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:53:06
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	11 Aug 2020 14:52:55
User entered 'un UNK 1990'	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Aug 2020 14:52:55

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 14:52:55



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:46:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:46:51
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	01 Oct 2020 22:59:42 01 Oct 2020 22:59:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:04:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:04:10
Data point term sent to Coder User entered 'meloxicam'	System (b) (4), (b) (6)	25 Sep 2020 16:35:37 25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'OSTEOARTHRITIS bilateral thumbs, left knee' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 22:59:07
User entered 'osteoarthritis'	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '15'	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:35:20



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'un UNK 2010'	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 16:35:20



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 16:35:20

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 16:35:20

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
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) (b) (4)	25 Sep 2020 17:05:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:05:56
Data point term sent to Coder	System	25 Sep 2020 16:37:42
User entered 'oxybutynin'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'overactive bladder'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '5'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:37:01



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'un Mar 2020'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:37:01



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 16:37:01

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 16:37:01

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Per CDM Requery: As data recorded, new medication Lisinopril started on 30AUG 2020 for hypertension. Please verify if this medication was added because the patient's medical history condition worsened. If yes, please add the worsening hypertension details on AE eCRF accordingly. Else clarify in query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 09:46:14
Query 'Per CDM Requery: As data recorded, new medication Lisinopril started on 30AUG 2020 for hypertension. Please verify if this medication was added because the patient's medical history condition worsened. If yes, please add the worsening hypertension details on AE eCRF accordingly. Else clarify in query response.' answered with 'per subject, her pcp did not give her lisinopril due to hypertension getting worse, rather, wanted to see if adding on another medication would improve her blood pressure.' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	12 Feb 2021 21:24:15
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:54:51
User opened query 'Per CDM Requery: As data recorded, new medication Lisinopril started on 30AUG 2020 for hypertension. Please verify if this medication was added because the patient's medical history condition worsened. If yes, please add the worsening hypertension details on AE eCRF accordingly. Else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:33:20
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Hypertension should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:33:20

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

Name of Medication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Hypertension should be recorded, and update con med indication or provide clarification. ' answered with 'stop date updated ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:20:39
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Hypertension should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:15:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:06:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:06:46
Data point term sent to Coder User entered 'Lisinopril'	System (b) (4), (b) (6)	25 Sep 2020 16:38:46 25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'hypertension'	(b) (4), (b) (6)	25 Sep 2020 16:38:12



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '10'	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:53:27**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '30 Aug 2020'	(b) (4), (b) (6)	25 Sep 2020 16:38:12



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Oct 2020 14:27:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Oct 2020 14:27:19
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:53:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:38:12

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User entered 'I'	System	25 Sep 2020 16:38:12

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User entered 'l'	System	25 Sep 2020 16:38:12

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:39
User entered '804 (804)'	System	25 Sep 2020 16:38:12

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
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.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:07:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:07:49
Data point term sent to Coder	System	25 Sep 2020 16:47:14
User entered 'tylenol'	(b) (4), (b) (6)	25 Sep 2020 16:47:10



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'AE of headache was added to AE log ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 07:01:12
	(b) (4), (b) (6)	15 Feb 2021 21:29:15
	(b) (4), (b) (6)	09 Feb 2021 20:54:51

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 09:36:36
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 14:29:08
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'take for solicited AE' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 20:41:21
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:15:13
User entered 'headache'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '500'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:47:10



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:53:27**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '5 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '8 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:53:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Dec 2020 20:41:07
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:47:10

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User entered 'l'	System	25 Sep 2020 16:47:10



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User entered 'I'	System	25 Sep 2020 16:47:10

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:43
User entered '804 (804)'	System	25 Sep 2020 16:47:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Mar 2021 20:30:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Mar 2021 20:30:56
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	10 Mar 2021 20:29:37 10 Mar 2021 20:29:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:54:51
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 18:41:09
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' answered with 'AE added to AE page' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:21:00
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:15:46

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 14:46:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 14:46:22
Data point term sent to Coder	System	10 Oct 2020 14:45:49
User entered 'lisinopril'	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 20:29:16
User entered 'worsening of HYPERTENSION' reason for change: New Information	(b) (4), (b) (6)	10 Mar 2021 20:29:16
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'hypertension'	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '20'	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Oct 2020 14:45:07



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '16 Sep 2020'	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 14:45:07



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Oct 2020 14:45:07

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Oct 2020 14:45:07

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS LEFT KNEE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:49:33
User closed query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple dosage strength options for this drug. Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:49:22
Query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple dosage strength options for this drug. Review and amend as appropriate.' answered with 'updated dose ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:22:37
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS LEFT KNEE should be recorded, and update con med indication or provide clarification. ' answered with 'not a worsening of ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:22:32
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS LEFT KNEE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:01:39
User opened query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple dosage strength options for this drug. Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:01:10

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:06:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:06:47
Data point term sent to Coder	System	27 Oct 2020 14:17:59
User entered 'Marcaine'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:17:03



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'Osteoarthritis left knee'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '5' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:22:18
User entered '2'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:22:18
User entered 'Other (OTHER)'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:22:18
User entered 'cc'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'once (ONCE)'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'Other (OTHER)'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'INTRA articular' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:17:35
User entered 'intra-articular'	(b) (4), (b) (6)	27 Oct 2020 14:17:03



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '7 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '7 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:53:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:17:03

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User entered empty.	System	27 Oct 2020 14:17:03

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User entered empty.	System	27 Oct 2020 14:17:03

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:50
User entered empty.	System	27 Oct 2020 14:17:03



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User closed query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple dosage strength options for this drug. Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:50:44
Query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple dosage strength options for this drug. Review and amend as appropriate. ' answered with 'updated dise ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:23:44
User opened query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple dosage strength options for this drug. Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:02:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: XYLOCAINE [LIDOCAINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:23:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:23:40
Data point term sent to Coder	System	27 Oct 2020 14:19:00
User entered 'xylocaine'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'osteoarthritis left knee'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '2.5' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:23:16
User entered 'l'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	25 Jan 2021 20:23:54
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	25 Jan 2021 20:23:16
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:23:16
User entered 'Other (OTHER)'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:23:54
User entered 'cc'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'once (ONCE)'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:18:31



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'Other (OTHER)'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'intra articular'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '7 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '7 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:53:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:18:31

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User entered empty.	System	27 Oct 2020 14:18:31



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User entered empty.	System	27 Oct 2020 14:18:31

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:54
User entered empty.	System	27 Oct 2020 14:18:31

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS LEFT KNEE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 01:54:56
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS LEFT KNEE should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	08 Mar 2021 17:31:33
' answered with 'not a worsening of' (Site from DM). User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS LEFT KNEE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:52:45
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:54:51
User closed query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple dosage strength options for this drug. Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:50:54
Query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple dosage strength options for this drug. Review and amend as appropriate. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:26:47

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple dosage strength options for this drug. Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:02:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, PRODUCT: BETAMETHASONE, PRODUCTSYNONYM: CELESTONE [BETAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 14:53:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 14:53:43
Data point term sent to Coder	System	27 Oct 2020 14:20:05
User entered 'celestone'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'osteoarthritis left knee'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '2'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:26:42
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	27 Oct 2020 14:19:51
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:19:51
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	27 Oct 2020 14:19:22
User entered 'puff (PUFF)'	(b) (4), (b) (6)	27 Oct 2020 14:19:22



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:26:42
User entered 'cc'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'once (ONCE)'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'Other (OTHER)'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'intra articular'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '7 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:53:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:19:22



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '7 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:53:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 14:19:22

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User entered empty.	System	27 Oct 2020 14:19:22

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User entered empty.	System	27 Oct 2020 14:19:22

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:11:59
User entered empty.	System	27 Oct 2020 14:19:22

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
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) (b) (4)	30 Oct 2020 21:30:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:30:02
Data point term sent to Coder	System	30 Oct 2020 21:29:48
User entered 'influenza vaccine'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'influenza prophylaxis'	(b) (4), (b) (6)	30 Oct 2020 21:29:16



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:27:07
User entered '0.52' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:27:02
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:27:02
User entered 'Other (OTHER)'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:53:54
Query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:27:13
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:27:02
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:03:16
User entered 'injection'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'once (ONCE)'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '25 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 21:29:16



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered '25 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:53:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:54:51
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 21:29:16

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User entered empty.	System	30 Oct 2020 21:29:16

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User entered empty.	System	30 Oct 2020 21:29:16

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:04
User entered empty.	System	30 Oct 2020 21:29:16

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 07:00:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:00:41
Data point term sent to Coder	System	05 Mar 2021 21:43:38
User entered 'Zithromax'	(b) (4), (b) (6)	05 Mar 2021 21:42:58



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'swollen right eye'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '500'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:53:27**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:53:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:42:58

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User entered empty.	System	05 Mar 2021 21:42:58

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User entered empty.	System	05 Mar 2021 21:42:58



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:10
User entered empty.	System	05 Mar 2021 21:42:58

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 07:00:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:00:41
Data point term sent to Coder	System	05 Mar 2021 21:44:39
User entered 'Zithromax'	(b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'swollen right eye'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '250'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:53:27**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56



US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '24 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:53:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:43:56



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User entered 'l'	System	05 Mar 2021 21:43:56

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User entered 'I'	System	05 Mar 2021 21:43:56

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:14
User entered '804 (804)'	System	05 Mar 2021 21:43:56

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:53:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: POLYMYXIN B - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 11:51:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:51:31
Data point term sent to Coder	System	05 Mar 2021 21:45:39
User entered 'polymyxin B drops'	(b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:53:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'swollen right eye'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '2'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'drops'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:53:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'ophthalmic'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14



US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 21:45:14

US3592075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:53:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Mar 2021 21:45:14

US3592075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:53:27

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:12:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:23:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Dec 2020 20:42:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:20:28
User entered 'No (N)'	(b) (4), (b) (6)	05 Sep 2020 17:30:56

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'USA-US103-2021-MRNA-1273-P301000003'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34



**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

US3592075

Folder: SAE USA-US103-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

US3592075

Folder: SAE USA-US103-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'Terry'	System	18 Feb 2021 19:35:34

US3592075

Folder: SAE USA-US103-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'Poling'	System	18 Feb 2021 19:35:34



**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered '1709 S Rock Rd'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'Wichita'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'KS'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered '67207'	System	18 Feb 2021 19:35:34

US3592075

Folder: SAE USA-US103-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
User entered 'US'	System	18 Feb 2021 19:36:24

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Feb 2021 19:36:24

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'USA-US103-2021-MRNA-1273-P301000003'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34



**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

US3592075

Folder: SAE USA-US103-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'No (N)'	System	18 Feb 2021 19:35:34

US3592075

Folder: SAE USA-US103-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'Terry'	System	18 Feb 2021 19:35:34

US3592075

Folder: SAE USA-US103-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:53:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'Poling'	System	18 Feb 2021 19:35:34



**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

**Site Address: [Street](#)**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered '1709 S Rock Rd'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

**Site Address: [City](#)**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'Wichita'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered 'KS'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:36:16
User entered '67207'	System	18 Feb 2021 19:35:34

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
User entered 'US'	System	18 Feb 2021 19:36:24

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:53:27**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Feb 2021 19:36:24

**US3592075**

**Folder: SAE USA-US103-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:53:27**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
User entered '18/Feb/2021 14:36'	System	18 Feb 2021 19:36:24

US3592075

Folder: SAE USA-US103-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:53:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:14:34
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	24 Feb 2021 17:14:39
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 19:36:24