

US3712174 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:29:06

All time stamps listed in this document are displayed in GMT

US3712174

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

Participant ID

US3712174

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

US3712174

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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	SCRN

US3712174

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3712174

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

US3712174

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	HEMORRHOIDS
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	HEMORRHOIDECTOMY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	HEMORRHOIDS
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	HEMORRHOIDECTOMY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	LEFT FOOT BREAK
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	LEFT FOOT REPAIR
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	BILATERAL MEDIAL COLLATERAL LIGAMENT TEAR
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	BILATERAL MEDIAL COLLATERAL LIGAMENT REPAIR
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	BILATERAL ANTERIOR CRUCIATE LIGAMENT TEAR
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	BILATERAL ANTERIOR CRUCIATE LIGAMENT REPAIR
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	LEFT KNEE FRACTURE
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	LEFT KNEE FRACTURE REPAIR
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Condition	DEGENERATIVE DISC DISEASE
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)	

US3712174

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:18 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 09:18
Height (<i>xxx.x</i>)	177.6 cm
Weight (<i>xxx.x</i>)	120.1 kg
BMI (<i>xxx.x</i>)	38.07651 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	59 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

RESTAURANTS AND SPORTING
EVENTS

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:42:56

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

What was the date of randomization? (dd MMM yyyy) 15 OCT 2020

What was the participant's randomization number? 116995

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Height	177.6 cm
Weight	121.0 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Height	177.6 cm
Weight	121.0 kg
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)	15 OCT 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 09:40
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Height	177.6 cm
Weight	121.0 kg
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)	15 OCT 2020
Time of assessment (00:00-23:59)	11:29 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 11:29
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

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) 15 OCT 2020

What was the treatment time? (00:00-23:59) 10:58 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 10:58

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	09:50 (24 HR)
Collection date and time (derived)	15 OCT 2020 09:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:52	15 OCT 2020 09:52
Nasopharyngeal Swab 2	No		

US3712174

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp 15 OCT 2020 11:35

PC Open Date & Time 15 OCT 2020 11:18

PC Close Date & Time 15 OCT 2020 13:48

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °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	15 OCT 2020 20:13
PC Open Date & Time	15 OCT 2020 14:43
PC Close Date & Time	16 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

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

16 OCT 2020 14:02

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 21:03

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

97.6 °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

18 OCT 2020 17:44

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 20 OCT 2020 00:29

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 20:23

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 22:21

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 11:36

PC Open Date & Time

15 OCT 2020 11:18

PC Close Date & Time

15 OCT 2020 13:48

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 20:14

PC Open Date & Time

15 OCT 2020 14:43

PC Close Date & Time

16 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

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

16 OCT 2020 14:02

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

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

17 OCT 2020 21:03

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

18 OCT 2020 17:45

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 00:29

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

20 OCT 2020 20:24

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

21 OCT 2020 22:22

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 11:37
PC Open Date & Time	15 OCT 2020 11:18
PC Close Date & Time	15 OCT 2020 13:48

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 20:15
PC Open Date & Time	15 OCT 2020 14:43
PC Close Date & Time	16 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

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 ☒

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 14:02
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 21:04
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 17:46
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

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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US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 00:29
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

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)

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 20:24
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

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 ☒

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	08:35 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 08:35
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 10:19
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3712174

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

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.

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 NOV 2020

What was the treatment time? (00:00-23:59) 09:44 (24 HR)

Treatment Date and Time (derived) 11 NOV 2020 09:44

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

What was the frequency of the study treatment dosing? ONCE

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

US3712174

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 NOV 2020
Collection time (00:00-23:59)	08:52 (24 HR)
Collection date and time (derived)	11 NOV 2020 08:52

US3712174

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 23:48:42

Generated On: 10 Jun 2021 09:29:06

Collection date (dd MMM yyyy)			11 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:55	11 NOV 2020 08:55
Nasopharyngeal Swab 2	No		

US3712174

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 NOV 2020 10:29

PC Open Date & Time

11 NOV 2020 10:04

PC Close Date & Time

11 NOV 2020 12:34

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

PC Time Stamp	11 NOV 2020 20:52
PC Open Date & Time	11 NOV 2020 13:29
PC Close Date & Time	12 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 NOV 2020 20:39

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 NOV 2020 22:23

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 NOV 2020 22:23

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 NOV 2020 20:02

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 NOV 2020 05:47

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 NOV 2020 19:20

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 NOV 2020 10:31

PC Open Date & Time

11 NOV 2020 10:04

PC Close Date & Time

11 NOV 2020 12:34

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 NOV 2020 20:53

PC Open Date & Time

11 NOV 2020 13:29

PC Close Date & Time

12 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 NOV 2020 20:39

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

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

13 NOV 2020 22:23

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

14 NOV 2020 22:23

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 NOV 2020 20:03

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

17 NOV 2020 05:47

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 NOV 2020 19:20

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

No ☒

Yes ☐

PC Time stamp	11 NOV 2020 10:31
PC Open Date & Time	11 NOV 2020 10:04
PC Close Date & Time	11 NOV 2020 12:34

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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

No ☒

Yes ☐

PC Time stamp	11 NOV 2020 20:53
PC Open Date & Time	11 NOV 2020 13:29
PC Close Date & Time	12 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	12 NOV 2020 20:39
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 2305

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	13 NOV 2020 22:24
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

113 of 2305

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	14 NOV 2020 22:24
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

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)

115 of 2305

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	15 NOV 2020 20:03
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

117 of 2305

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 05:48
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

119 of 2305

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 19:21
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3712174

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:42:56

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	VISIT3

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3712174

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

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.

US3712174

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:42:57

Generated On: 10 Jun 2021 09:29:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 DEC 2020
Collection time (00:00-23:59)	07:50 (24 HR)
Collection date and time (derived)	09 DEC 2020 07:50

US3712174

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 02:35:14

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 152

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 187

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 type="radio"/>
Have you been exposed to someone with known SARS-CoV-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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 OCT 2021 00:01
Patient Cloud Close Date & Time	06 OCT 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐
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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 516

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

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

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

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐ 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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐
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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Patient Cloud Open Date & Time	27 AUG 2022 00:01
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Patient Cloud Close Date & Time	31 AUG 2022 23:59
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US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Patient Cloud Open Date & Time	22 OCT 2022 00:01
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Patient Cloud Close Date & Time	26 OCT 2022 23:59
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US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐ 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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

DAY 761

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

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

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

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

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

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Patient Cloud Open Date & Time	12 NOV 2022 00:01
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Patient Cloud Close Date & Time	16 NOV 2022 23:59
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US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

26 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

[Patient Cloud Open Date & Time](#)

03 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2022 00:01
Patient Cloud Close Date & Time	14 DEC 2022 23:59

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2022 23:59

US3712174

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 02:35:14

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 02:35:13

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 23:30:09

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 23:30:09

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3712174

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3712174

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

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.

US3712174

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3712174

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

Date of Contact	23 OCT 2020
Time of Contact	18:00
Date and Time of Contact (derived)	23 OCT 2020 18:00
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>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 OCT 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

	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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 OCT 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

	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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 OCT 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 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 23 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

	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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 OCT 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 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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

	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 OCT 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 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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"/>

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

Date of Visit 23 OCT 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

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)

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3712174

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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

Visit date (dd MMM yyyy)	23 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	SICKD1
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US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Height (xxx.x) _____

Weight (xxx.x) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3712174

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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.

US3712174

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Apr 2021 01:12:06

Generated On: 10 Jun 2021 09:29:06

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID SICKD28

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:37:17

Generated On: 10 Jun 2021 09:29:06

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.

US3712174

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3712174

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

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

Visit date (dd MMM yyyy)	26 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3712174

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Date of updated informed consent (<i>dd MMM yyyy</i>)	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3712174

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

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

US3712174

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Height	ND - Not Done
Weight	ND - Not Done
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)	26 JAN 2021
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 13:37
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3712174

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Height	ND - Not Done
Weight	ND - Not Done
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)	26 JAN 2021
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 14:55
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3712174

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

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.

US3712174

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

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) 26 JAN 2021

What was the treatment time? (00:00-23:59) 14:22 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 14:22

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

US3712174

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

12:57 (24 HR)

Collection date and time (derived)

26 JAN 2021 12:57

US3712174

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	12:58
Collection Date and Time (derived)	26 JAN 2021 12:58

US3712174

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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)	01 MAR 2021
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 08:40
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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)	01 MAR 2021
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 10:16
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)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3712174

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 MAR 2021

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

US3712174

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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) 01 MAR 2021

What was the treatment time? (00:00-23:59) 09:46 (24 HR)

Treatment Date and Time (derived) 01 MAR 2021 09:46

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

US3712174

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712174

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712174

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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

Visit date (dd MMM yyyy)	29 MAR 2021
--------------------------	-------------

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

Folder OID	OLD57
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US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3712174

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

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.

US3712174

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 00:37:47

Generated On: 10 Jun 2021 09:29:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 MAR 2021
Collection time (00:00-23:59)	13:22 (24 HR)
Collection date and time (derived)	29 MAR 2021 13:22

US3712174

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 22:25:03

Generated On: 10 Jun 2021 09:29:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

AEID	USA-US068-2021-MRNA-1273-P30 1000016
Adverse event	WORSENING OF DEGENERATIVE DISC DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	13 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

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	False
Concomitant Procedure	True
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	

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

ON 01 MARCH 2021 SUBJECT
WAS IN CLINIC FOR OLV-2 AND
REPORTED THAT THEY WERE
HOSPITALIZED ON 11
FEBRUARY 2021 DUE TO
WORSENING OF
DEGENERATIVE DISC DISEASE
THAT BEGAN IN 2010. ON 11
FEBRUARY 2021 SUBJECT WAS
ADMITTED TO FORT SANDERS
REGIONAL MEDICAL CENTER
FOR ANTERIOR DISCECTOMY
CERVICAL FUSION OF C4, C5,
C6, C7 WAS ILIAC CREST DONE
GRAFTING AND ANTERIOR
PLATING OF C4 AND C7.
SUBJECT STAYED IN HOSPITAL
FOR 2 DAYS AND WAS
DISCHARGED HOME. PENDING
MEDICAL RECORDS FOR
ADDITIONAL INFORMATION.

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

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

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

Yes ☒

No ☐

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

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

	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 2003	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

	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 2003	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

	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 (4)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 (4)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

	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 2012	
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"/>

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

Name of Medication INDOMETHACIN

Prophylaxis Yes ☐
No ☒

Indication GOUT

Dose per administration 50

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) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

	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)	28 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication GOUT

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

	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)	28 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

	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)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	28 NOV 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"/>	

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

Name of Medication HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication QUADRUPLE CERVICAL
FUSION WITH BONE GRAFT

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

EVERY 6 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712174

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Apr 2021 21:42:21

Generated On: 10 Jun 2021 09:29:06

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3712174

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 00:37:16

Generated On: 10 Jun 2021 09:29:06

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 FEB 2021	ANTERIOR DISCECTOMY CERVICAL FUSION OF C4, C5, C6, C7	Adverse Event	

US3712174

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:29:06

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

US3712174

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:29:06

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 ☐

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

SAEID	USA-US068-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

SAEID	USA-US068-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	02/MAR/2021 09:39
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

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 00:37:48

Generated On: 10 Jun 2021 09:29:06

SAEID	USA-US068-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	18/MAR/2021 12:44
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

US3712174 (Prod: Alliance for Multispecialty Research, LLC)

US3712174

Form: Participant Creation

Generated On: 10 Jun 2021 09:29:06

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'US3712174'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 12:44:04

US3712174

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:12

US3712174

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '12 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 12:44:06

US3712174

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:12

US3712174

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'SCRN'	System	15 Oct 2020 15:10:12

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered (b) (6) 1967'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 12:44:07

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '53'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'YEARS'	System	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '53'	System	15 Oct 2020 15:10:53

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:06

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:30

US3712174

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:06

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:53

US3712174

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Oct 2020'	System	15 Oct 2020 15:10:53

US3712174

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2020'	System	15 Oct 2020 15:10:53

US3712174

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:06

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Amendment 4 (4)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:53

US3712174

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:53

US3712174

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:53

US3712174

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:53

US3712174

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:10:53

US3712174

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 12:44:06

US3712174

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'I'	System	15 Oct 2020 15:11:13

US3712174

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:11:13

US3712174

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:29:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:46

US3712174

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
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)	15 Oct 2020 16:46:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:46:25
Data point term sent to Coder	System	15 Oct 2020 16:45:45
User entered 'seasonal allergies'	(b) (4), (b) (6)	15 Oct 2020 16:45:20

US3712174

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:20

US3712174

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:20

US3712174

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:20

US3712174

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:20

US3712174

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:20

US3712174

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2012'	System	15 Oct 2020 16:45:20

US3712174

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2012'	System	15 Oct 2020 16:45:20

US3712174

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	15 Oct 2020 16:45:20

US3712174

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	15 Oct 2020 16:45:20

US3712174

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:46:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:46:25
Data point term sent to Coder	System	15 Oct 2020 16:45:45
User entered 'myopia'	(b) (4), (b) (6)	15 Oct 2020 16:45:35

US3712174

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:35

US3712174

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:35

US3712174

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:35

US3712174

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:35

US3712174

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:35

US3712174

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2000'	System	15 Oct 2020 16:45:35

US3712174

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2000'	System	15 Oct 2020 16:45:35

US3712174

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	15 Oct 2020 16:45:35

US3712174

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	15 Oct 2020 16:45:35

US3712174

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:47:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:47:28
Data point term sent to Coder	System	15 Oct 2020 16:46:46
User entered 'hypertension'	(b) (4), (b) (6)	15 Oct 2020 16:45:48

US3712174

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:48

US3712174

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:48

US3712174

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:48

US3712174

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:48

US3712174

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:45:48

US3712174

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 16:45:48

US3712174

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 16:45:48

US3712174

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	15 Oct 2020 16:45:48

US3712174

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	15 Oct 2020 16:45:48

US3712174

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
Query 'Per DM CLR: Please specify the location of GOUT (DIET CONTROLLED). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:42:49
User opened query 'Per DM CLR: Please specify the location of GOUT (DIET CONTROLLED). 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)	29 Oct 2020 03:29:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 23:31:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 23:31:34
Data point term sent to Coder	System	15 Oct 2020 16:46:46
User entered 'Gout (diet controlled)'	(b) (4), (b) (6)	15 Oct 2020 16:46:13

US3712174

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:13

US3712174

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:13

US3712174

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:13

US3712174

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:13

US3712174

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:13

US3712174

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2013'	System	15 Oct 2020 16:46:13

US3712174

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2013'	System	15 Oct 2020 16:46:13

US3712174

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	15 Oct 2020 16:46:13

US3712174

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	15 Oct 2020 16:46:13

US3712174

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:48:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:48:30
Data point term sent to Coder	System	15 Oct 2020 16:47:47
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	15 Oct 2020 16:46:51

US3712174

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:51

US3712174

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:51

US3712174

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:51

US3712174

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:51

US3712174

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:46:51

US3712174

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2005'	System	15 Oct 2020 16:46:51

US3712174

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2005'	System	15 Oct 2020 16:46:51

US3712174

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	15 Oct 2020 16:46:51

US3712174

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	15 Oct 2020 16:46:51

US3712174

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:48:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:48:31
Data point term sent to Coder	System	15 Oct 2020 16:47:48
User entered 'cholecystitis'	(b) (4), (b) (6)	15 Oct 2020 16:47:26

US3712174

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:26

US3712174

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:26

US3712174

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:26

US3712174

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:26

US3712174

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:26

US3712174

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2007'	System	15 Oct 2020 16:47:26

US3712174

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2007'	System	15 Oct 2020 16:47:26

US3712174

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2007'	System	15 Oct 2020 16:47:26

US3712174

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2007'	System	15 Oct 2020 16:47:26

US3712174

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:49:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:49:33
Data point term sent to Coder	System	15 Oct 2020 16:48:49
User entered 'cholecystectomy'	(b) (4), (b) (6)	15 Oct 2020 16:47:54

US3712174

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:54

US3712174

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:54

US3712174

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:54

US3712174

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:54

US3712174

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:47:54

US3712174

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2007'	System	15 Oct 2020 16:47:54

US3712174

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2007'	System	15 Oct 2020 16:47:54

US3712174

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2007'	System	15 Oct 2020 16:47:54

US3712174

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2007'	System	15 Oct 2020 16:47:54

US3712174

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:49:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:49:33
Data point term sent to Coder	System	15 Oct 2020 16:48:50
User entered 'hemorrhoids'	(b) (4), (b) (6)	15 Oct 2020 16:48:44

US3712174

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 1999'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:44

US3712174

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:44

US3712174

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:44

US3712174

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 1999'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:44

US3712174

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:48:44

US3712174

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 1999'	System	15 Oct 2020 16:48:44

US3712174

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '1999'	System	15 Oct 2020 16:48:44

US3712174

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 1999'	System	15 Oct 2020 16:48:44

US3712174

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '1999'	System	15 Oct 2020 16:48:44

US3712174

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Anorectal therapeutic procedures, PT: Haemorrhoid operation, LLT: Hemorrhoidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:50:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:50:30
Data point term sent to Coder	System	15 Oct 2020 16:49:51
User entered 'hemorrhoidectomy'	(b) (4), (b) (6)	15 Oct 2020 16:49:10

US3712174

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 1999'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:10

US3712174

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:10

US3712174

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:10

US3712174

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 1999'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:10

US3712174

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:10

US3712174

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 1999'	System	15 Oct 2020 16:49:10

US3712174

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '1999'	System	15 Oct 2020 16:49:10

US3712174

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 1999'	System	15 Oct 2020 16:49:10

US3712174

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '1999'	System	15 Oct 2020 16:49:10

US3712174

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:50:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:50:30
Data point term sent to Coder	System	15 Oct 2020 16:49:51
User entered 'hemorrhoids'	(b) (4), (b) (6)	15 Oct 2020 16:49:22

US3712174

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:22

US3712174

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:22

US3712174

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:22

US3712174

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:22

US3712174

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:22

US3712174

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2005'	System	15 Oct 2020 16:49:22

US3712174

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2005'	System	15 Oct 2020 16:49:22

US3712174

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2005'	System	15 Oct 2020 16:49:22

US3712174

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2005'	System	15 Oct 2020 16:49:22

US3712174

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Anorectal therapeutic procedures, PT: Haemorrhoid operation, LLT: Hemorrhoidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:50:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:50:30
Data point term sent to Coder	System	15 Oct 2020 16:49:51
User entered 'hemorrhoidectomy'	(b) (4), (b) (6)	15 Oct 2020 16:49:33

US3712174

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:33

US3712174

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:33

US3712174

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:33

US3712174

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:33

US3712174

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:33

US3712174

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2005'	System	15 Oct 2020 16:49:33

US3712174

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2005'	System	15 Oct 2020 16:49:33

US3712174

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2005'	System	15 Oct 2020 16:49:33

US3712174

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2005'	System	15 Oct 2020 16:49:33

US3712174

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:50:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:50:29
Data point term sent to Coder	System	15 Oct 2020 16:49:52
User entered 'hemorrhoids'	(b) (4), (b) (6)	15 Oct 2020 16:49:50

US3712174

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:50

US3712174

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:50

US3712174

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:50

US3712174

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:50

US3712174

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:49:50

US3712174

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2015'	System	15 Oct 2020 16:49:50

US3712174

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2015'	System	15 Oct 2020 16:49:50

US3712174

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2015'	System	15 Oct 2020 16:49:50

US3712174

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2015'	System	15 Oct 2020 16:49:50

US3712174

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Anorectal therapeutic procedures, PT: Haemorrhoid operation, LLT: Hemorrhoidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:51:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:51:33
Data point term sent to Coder	System	15 Oct 2020 16:50:53
User entered 'hemorrhoidectomy'	(b) (4), (b) (6)	15 Oct 2020 16:50:06

US3712174

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:50:06

US3712174

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:50:06

US3712174

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:50:06

US3712174

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:50:06

US3712174

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:50:06

US3712174

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2015'	System	15 Oct 2020 16:50:06

US3712174

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2015'	System	15 Oct 2020 16:50:06

US3712174

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2015'	System	15 Oct 2020 16:50:06

US3712174

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2015'	System	15 Oct 2020 16:50:06

US3712174

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\23.0.	Coder Import (b) (4)	16 Oct 2020 12:28:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Oct 2020 12:28:31
Data point term sent to Coder	System	15 Oct 2020 17:02:23
User entered 'left foot break'	(b) (4), (b) (6)	15 Oct 2020 17:01:38

US3712174

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:38

US3712174

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:38

US3712174

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:38

US3712174

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:38

US3712174

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:38

US3712174

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2015'	System	15 Oct 2020 17:01:38

US3712174

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2015'	System	15 Oct 2020 17:01:38

US3712174

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2015'	System	15 Oct 2020 17:01:38

US3712174

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2015'	System	15 Oct 2020 17:01:38

US3712174

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Foot operation, LLT: Foot operation - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 17:03:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 17:03:26
Data point term sent to Coder	System	15 Oct 2020 17:02:24
User entered 'left foot repair'	(b) (4), (b) (6)	15 Oct 2020 17:01:56

US3712174

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:56

US3712174

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:56

US3712174

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:56

US3712174

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:56

US3712174

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:56

US3712174

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2015'	System	15 Oct 2020 17:01:56

US3712174

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2015'	System	15 Oct 2020 17:01:56

US3712174

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2015'	System	15 Oct 2020 17:01:56

US3712174

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2015'	System	15 Oct 2020 17:01:56

US3712174

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament rupture, LLT: Ligament tear - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 04:57:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 04:57:27
Data point term sent to Coder	System	15 Oct 2020 17:03:25
User entered 'bilateral medial collateral ligament tear'	(b) (4), (b) (6)	15 Oct 2020 17:02:58

US3712174

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:02:58

US3712174

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:02:58

US3712174

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:02:58

US3712174

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:02:58

US3712174

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:02:58

US3712174

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:02:58

US3712174

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:02:58

US3712174

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:02:58

US3712174

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:02:58

US3712174

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ligament operation, LLT: Ligament repair - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 04:57:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 04:57:27
Data point term sent to Coder	System	15 Oct 2020 17:03:25
User entered 'bilateral medial collateral ligament repair'	(b) (4), (b) (6)	15 Oct 2020 17:03:13

US3712174

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:03:13

US3712174

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:03:13

US3712174

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:03:13

US3712174

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:03:13

US3712174

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:03:13

US3712174

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:03:13

US3712174

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:03:13

US3712174

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:03:13

US3712174

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:03:13

US3712174

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament rupture, LLT: Anterior cruciate ligament tear - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 21:04:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 21:04:43
Data point term sent to Coder	System	15 Oct 2020 17:05:27
User entered 'bilateral anterior cruciate ligament tear'	(b) (4), (b) (6)	15 Oct 2020 17:04:45

US3712174

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:04:45

US3712174

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:04:45

US3712174

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:04:45

US3712174

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:04:45

US3712174

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:04:45

US3712174

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:04:45

US3712174

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:04:45

US3712174

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:04:45

US3712174

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:04:45

US3712174

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ligament operation, LLT: Anterior cruciate ligament reconstruction - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 04:56:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 04:56:28
Data point term sent to Coder	System	15 Oct 2020 17:05:30
User entered 'bilateral anterior cruciate ligament repair'	(b) (4), (b) (6)	15 Oct 2020 17:05:03

US3712174

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:03

US3712174

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:03

US3712174

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:03

US3712174

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:03

US3712174

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:03

US3712174

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:05:03

US3712174

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:05:03

US3712174

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:05:03

US3712174

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:05:03

US3712174

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:29:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Lower limb fracture, LLT: Knee fracture - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 17:06:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 17:06:37
Data point term sent to Coder	System	15 Oct 2020 17:05:30
User entered 'left knee fracture'	(b) (4), (b) (6)	15 Oct 2020 17:05:26

US3712174

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:26

US3712174

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:26

US3712174

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:26

US3712174

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:26

US3712174

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:26

US3712174

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:05:26

US3712174

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:05:26

US3712174

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:05:26

US3712174

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:05:26

US3712174

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:29:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 13:24:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 13:24:45
Data point term sent to Coder	System	15 Oct 2020 17:06:30
User entered 'left knee fracture repair'	(b) (4), (b) (6)	15 Oct 2020 17:05:51

US3712174

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:51

US3712174

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:51

US3712174

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:51

US3712174

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:51

US3712174

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:05:51

US3712174

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:05:51

US3712174

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:05:51

US3712174

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2003'	System	15 Oct 2020 17:05:51

US3712174

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2003'	System	15 Oct 2020 17:05:51

US3712174

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:29:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:48:42
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)	17 Mar 2021 19:46:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 19:46:48
Data point term sent to Coder	System	17 Mar 2021 19:45:29
User entered 'DEGENERATIVE DISC DISEASE'	(b) (4), (b) (6)	17 Mar 2021 19:44:34

US3712174

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:48:42
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:44:34

US3712174

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:48:42
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:44:34

US3712174

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:29:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:48:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:44:34

US3712174

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:48:42
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:44:34

US3712174

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:29:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:48:42
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:44:34

US3712174

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'Jan 2010'	System	17 Mar 2021 19:44:34

US3712174

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '2010'	System	17 Mar 2021 19:44:34

US3712174

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	17 Mar 2021 19:44:34

US3712174

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered empty.	System	17 Mar 2021 19:44:34

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	15 Oct 2020 16:40:34
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	15 Oct 2020 16:40:34
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 16:40:34
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Oct 2020 16:37:53
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Oct 2020 16:39:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Oct 2020 16:39:59
User entered '09:18' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 16:39:59
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 16:37:53
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '12 Oct 2020 09:18'	System	15 Oct 2020 16:40:34
User entered '15 Oct 2020 09:18'	System	15 Oct 2020 16:39:59
User entered empty.	System	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '177.6' cm	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:37:53
DataPoint set to visible.	System	15 Oct 2020 15:11:13

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '120.1' kg reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:38:33
User entered '121.0' kg	(b) (4), (b) (6)	15 Oct 2020 16:37:53
DataPoint set to visible.	System	15 Oct 2020 15:11:13

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered '38.07651'	System	15 Oct 2020 16:38:33
User entered '38.36184'	System	15 Oct 2020 16:37:53
DataPoint set to visible.	System	15 Oct 2020 15:11:13

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'kg/m2'	System	15 Oct 2020 16:37:53
DataPoint set to visible.	System	15 Oct 2020 15:11:13

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Oct 2020 16:39:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Oct 2020 16:39:59
User entered '36.6' C reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 16:39:59
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 16:37:53
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:39:59
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Oct 2020 16:39:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Oct 2020 16:39:59
User entered '59' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 16:39:59
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 16:37:53
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'bpm'	System	15 Oct 2020 16:39:59
User entered empty.	System	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Oct 2020 16:39:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Oct 2020 16:39:59
User entered '17' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 16:39:59
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 16:37:53
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'breaths/min'	System	15 Oct 2020 16:39:59
User entered empty.	System	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Oct 2020 16:39:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Oct 2020 16:39:59
User entered '131' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 16:39:59
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 16:37:53
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'mmHg'	System	15 Oct 2020 16:39:59
User entered empty.	System	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Oct 2020 16:39:59
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Oct 2020 16:39:59
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 16:39:59
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 16:37:53
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User entered 'mmHg'	System	15 Oct 2020 16:39:59
User entered empty.	System	15 Oct 2020 16:37:53

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47

US3712174

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47

US3712174

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:40:41

US3712174

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:40:41

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

[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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

[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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'restaurants and sporting events'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

[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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

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)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:57:47
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Lives with individuals who are at occupational risk for exposure.'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:44:16

US3712174

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:11:41

US3712174

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:11:41

US3712174

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:11:41

US3712174

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'VISIT1'	System	15 Oct 2020 15:11:41

US3712174

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '15 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 14:38:59

US3712174

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:06

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '116995'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 14:38:59

US3712174

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:06

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 14:38:59

US3712174

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:06

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)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:12:50

US3712174

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:06

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)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:12:50

US3712174

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:06

[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:12:50

US3712174

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:06

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:12:50

US3712174

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:06

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:12:50

US3712174

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:06

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:12:50
DataPoint set to visible.	System	15 Oct 2020 15:10:53

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '177.6' cm	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '121.0' kg	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '177.6' cm	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '121.0' kg	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '09:40'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered '15 Oct 2020 09:40'	System	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '71'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'bpm'	System	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'breaths/min'	System	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '135'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'mmHg'	System	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '84'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'mmHg'	System	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '177.6' cm	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '121.0' kg	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '11:29'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered '15 Oct 2020 11:29'	System	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '61'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'bpm'	System	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'breaths/min'	System	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '112'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'mmHg'	System	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '72'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'mmHg'	System	15 Oct 2020 17:11:50

US3712174

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:01

US3712174

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:01

US3712174

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:42

US3712174

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:42

US3712174

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

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)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:42

US3712174

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 15:13:42

US3712174

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:42

US3712174

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '10:58'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:42

US3712174

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered '15 Oct 2020 10:58'	System	15 Oct 2020 15:13:42

US3712174

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:42

US3712174

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'ONCE'	System	15 Oct 2020 15:13:42

US3712174

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 15:13:42

US3712174

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:11

US3712174

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:11

US3712174

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '09:50'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:11

US3712174

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered '15 Oct 2020 09:50'	System	15 Oct 2020 15:13:11

US3712174

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:29:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:20

US3712174

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Oct 2020 15:13:20

US3712174

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:20

US3712174

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '09:52'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:20

US3712174

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered '15 Oct 2020 09:52'	System	15 Oct 2020 15:13:20

US3712174

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Oct 2020 15:13:20

US3712174

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:48:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:09:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 19:09:45
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:20

US3712174

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:48:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:09:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 19:09:45
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '09:52'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:20

US3712174

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered empty.	System	12 Mar 2021 19:09:45
User entered '15 Oct 2020 09:52'	System	15 Oct 2020 15:13:20

US3712174

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:13:23

US3712174

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'I'	System	15 Oct 2020 15:13:23

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:34:30', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '11f11ce4-d0b8-42a6-b64c-0c1cdadae5be'	System	15 Oct 2020 15:35:23
User entered 'Yes (Y)'	System	15 Oct 2020 15:35:23

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:34:56', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '11f11ce4-d0b8-42a6-b64c-0c1cdadae5be'	System	15 Oct 2020 15:35:23
User entered '98.4'	System	15 Oct 2020 15:35:23

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:35:05', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '11f11ce4-d0b8-42a6-b64c-0c1cdadae5be'	System	15 Oct 2020 15:35:23
User entered 'No (N)'	System	15 Oct 2020 15:35:23

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:35:20', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '11f11ce4-d0b8-42a6-b64c-0c1cdadae5be'	System	15 Oct 2020 15:35:23
User entered '15 Oct 2020 11:35'	System	15 Oct 2020 15:35:23

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Oct 2020 11:18'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Oct 2020 13:48'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:12:48', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '9b69d04a-3ca5-4c02-92a7-dba606859c10'	System	16 Oct 2020 00:13:35
User entered 'Yes (Y)'	System	16 Oct 2020 00:13:35

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:13:17', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '9b69d04a-3ca5-4c02-92a7-dba606859c10'	System	16 Oct 2020 00:13:35
User entered '97.7'	System	16 Oct 2020 00:13:35

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:13:21', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '9b69d04a-3ca5-4c02-92a7-dba606859c10'	System	16 Oct 2020 00:13:35
User entered 'No (N)'	System	16 Oct 2020 00:13:35

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:13:30', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '9b69d04a-3ca5-4c02-92a7-dba606859c10'	System	16 Oct 2020 00:13:35
User entered '15 Oct 2020 20:13'	System	16 Oct 2020 00:13:35

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Oct 2020 14:43'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 2'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:01:52', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '2d311662-fc26-4d4d-8efd-791d488d7a8a'	System	16 Oct 2020 18:02:14
User entered 'Yes (Y)'	System	16 Oct 2020 18:02:14

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:02', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '2d311662-fc26-4d4d-8efd-791d488d7a8a'	System	16 Oct 2020 18:02:14
User entered '97.8'	System	16 Oct 2020 18:02:14

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:06', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '2d311662-fc26-4d4d-8efd-791d488d7a8a'	System	16 Oct 2020 18:02:14
User entered 'No (N)'	System	16 Oct 2020 18:02:14

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:12', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '2d311662-fc26-4d4d-8efd-791d488d7a8a'	System	16 Oct 2020 18:02:14
User entered '16 Oct 2020 14:02'	System	16 Oct 2020 18:02:14

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 3'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:02:59', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '80ef8744-f60c-4670-b1c9-751a9fd0c74d'	System	18 Oct 2020 01:03:38
User entered 'Yes (Y)'	System	18 Oct 2020 01:03:38

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:03:23', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '80ef8744-f60c-4670-b1c9-751a9fd0c74d'	System	18 Oct 2020 01:03:38
User entered '98.2'	System	18 Oct 2020 01:03:38

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:03:27', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '80ef8744-f60c-4670-b1c9-751a9fd0c74d'	System	18 Oct 2020 01:03:38
User entered 'No (N)'	System	18 Oct 2020 01:03:38

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:03:32', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '80ef8744-f60c-4670-b1c9-751a9fd0c74d'	System	18 Oct 2020 01:03:38
User entered '17 Oct 2020 21:03'	System	18 Oct 2020 01:03:38

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 4'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:43:58', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'beb83603-2d6a-4c38-85f8-32b00019ccd8'	System	18 Oct 2020 21:44:38
User entered 'Yes (Y)'	System	18 Oct 2020 21:44:38

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:44:15', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'beb83603-2d6a-4c38-85f8-32b00019ccd8'	System	18 Oct 2020 21:44:38
User entered '97.6'	System	18 Oct 2020 21:44:38

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:44:28', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'beb83603-2d6a-4c38-85f8-32b00019ccd8'	System	18 Oct 2020 21:44:38
User entered 'No (N)'	System	18 Oct 2020 21:44:38

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:44:33', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'beb83603-2d6a-4c38-85f8-32b00019ccd8'	System	18 Oct 2020 21:44:38
User entered '18 Oct 2020 17:44'	System	18 Oct 2020 21:44:38

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 5'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:28:58', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '9710e0a2-85cf-4b8f-b735-77876ebd161e'	System	20 Oct 2020 04:29:08
User entered 'No (N)'	System	20 Oct 2020 04:29:08

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:01', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '9710e0a2-85cf-4b8f-b735-77876ebd161e'	System	20 Oct 2020 04:29:08
User entered 'No (N)'	System	20 Oct 2020 04:29:08

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:04', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '9710e0a2-85cf-4b8f-b735-77876ebd161e'	System	20 Oct 2020 04:29:08
User entered '20 Oct 2020 00:29'	System	20 Oct 2020 04:29:08

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 6'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:23:31', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '0e6d7148-f13b-489f-b550-51c338fb11de'	System	21 Oct 2020 00:23:55
User entered 'Yes (Y)'	System	21 Oct 2020 00:23:55

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:23:40', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '0e6d7148-f13b-489f-b550-51c338fb11de'	System	21 Oct 2020 00:23:55
User entered '97.2'	System	21 Oct 2020 00:23:55

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:23:45', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '0e6d7148-f13b-489f-b550-51c338fb11de'	System	21 Oct 2020 00:23:55
User entered 'No (N)'	System	21 Oct 2020 00:23:55

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:23:49', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '0e6d7148-f13b-489f-b550-51c338fb11de'	System	21 Oct 2020 00:23:55
User entered '20 Oct 2020 20:23'	System	21 Oct 2020 00:23:55

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 7'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:21:23', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '36b5efda-c7ca-4d36-8d0e-e5bc10559d06'	System	22 Oct 2020 02:21:41
User entered 'Yes (Y)'	System	22 Oct 2020 02:21:41

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:21:28', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '36b5efda-c7ca-4d36-8d0e-e5bc10559d06'	System	22 Oct 2020 02:21:41
User entered '98.3'	System	22 Oct 2020 02:21:41

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:21:34', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '36b5efda-c7ca-4d36-8d0e-e5bc10559d06'	System	22 Oct 2020 02:21:41
User entered 'No (N)'	System	22 Oct 2020 02:21:41

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:21:37', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '36b5efda-c7ca-4d36-8d0e-e5bc10559d06'	System	22 Oct 2020 02:21:41
User entered '21 Oct 2020 22:21'	System	22 Oct 2020 02:21:41

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:04', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '4eed26e7-7eb6-48bd-bbb9-33f50985a002'	System	15 Oct 2020 15:36:24
User entered 'None (1)'	System	15 Oct 2020 15:36:24

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:08', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '4eed26e7-7eb6-48bd-bbb9-33f50985a002'	System	15 Oct 2020 15:36:24
User entered 'No (N)'	System	15 Oct 2020 15:36:24

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:11', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '4eed26e7-7eb6-48bd-bbb9-33f50985a002'	System	15 Oct 2020 15:36:24
User entered 'No (N)'	System	15 Oct 2020 15:36:24

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:14', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '4eed26e7-7eb6-48bd-bbb9-33f50985a002'	System	15 Oct 2020 15:36:24
User entered 'None (1)'	System	15 Oct 2020 15:36:24

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:18', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '4eed26e7-7eb6-48bd-bbb9-33f50985a002'	System	15 Oct 2020 15:36:24
User entered '15 Oct 2020 11:36'	System	15 Oct 2020 15:36:24

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Oct 2020 11:18'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Oct 2020 13:48'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:13:43', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5c9e3382-68a1-4352-a7ce-d62cf08c8980'	System	16 Oct 2020 00:14:19
User entered 'None (1)'	System	16 Oct 2020 00:14:19

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:13:52', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5c9e3382-68a1-4352-a7ce-d62cf08c8980'	System	16 Oct 2020 00:14:19
User entered 'No (N)'	System	16 Oct 2020 00:14:19

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:14:00', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5c9e3382-68a1-4352-a7ce-d62cf08c8980'	System	16 Oct 2020 00:14:19
User entered 'No (N)'	System	16 Oct 2020 00:14:19

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:14:07', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5c9e3382-68a1-4352-a7ce-d62cf08c8980'	System	16 Oct 2020 00:14:19
User entered 'None (1)'	System	16 Oct 2020 00:14:19

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:14:16', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5c9e3382-68a1-4352-a7ce-d62cf08c8980'	System	16 Oct 2020 00:14:19
User entered '15 Oct 2020 20:14'	System	16 Oct 2020 00:14:19

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Oct 2020 14:43'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 2'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:17', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '4cff8c07-74e7-4ec3-ad38-8082ec177a93'	System	16 Oct 2020 18:02:38
User entered 'None (1)'	System	16 Oct 2020 18:02:38

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:21', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '4cff8c07-74e7-4ec3-ad38-8082ec177a93'	System	16 Oct 2020 18:02:38
User entered 'No (N)'	System	16 Oct 2020 18:02:38

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:23', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '4cff8c07-74e7-4ec3-ad38-8082ec177a93'	System	16 Oct 2020 18:02:38
User entered 'No (N)'	System	16 Oct 2020 18:02:38

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:27', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '4cff8c07-74e7-4ec3-ad38-8082ec177a93'	System	16 Oct 2020 18:02:38
User entered 'None (1)'	System	16 Oct 2020 18:02:38

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:30', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '4cff8c07-74e7-4ec3-ad38-8082ec177a93'	System	16 Oct 2020 18:02:38
User entered '16 Oct 2020 14:02'	System	16 Oct 2020 18:02:38

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 3'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:03:39', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '0a7e5f6b-67a0-48ce-866e-4b194e8c6374'	System	18 Oct 2020 01:03:54
User entered 'None (1)'	System	18 Oct 2020 01:03:54

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:03:42', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '0a7e5f6b-67a0-48ce-866e-4b194e8c6374'	System	18 Oct 2020 01:03:54
User entered 'No (N)'	System	18 Oct 2020 01:03:54

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:03:45', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '0a7e5f6b-67a0-48ce-866e-4b194e8c6374'	System	18 Oct 2020 01:03:54
User entered 'No (N)'	System	18 Oct 2020 01:03:54

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:03:49', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '0a7e5f6b-67a0-48ce-866e-4b194e8c6374'	System	18 Oct 2020 01:03:54
User entered 'None (1)'	System	18 Oct 2020 01:03:54

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:03:52', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '0a7e5f6b-67a0-48ce-866e-4b194e8c6374'	System	18 Oct 2020 01:03:54
User entered '17 Oct 2020 21:03'	System	18 Oct 2020 01:03:54

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 4'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:44:37', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'abe5276f-b9ea-4f48-ae04-3f001b04124f'	System	18 Oct 2020 21:45:27
User entered 'None (1)'	System	18 Oct 2020 21:45:27

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:44:47', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'abe5276f-b9ea-4f48-ae04-3f001b04124f'	System	18 Oct 2020 21:45:27
User entered 'No (N)'	System	18 Oct 2020 21:45:27

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:44:50', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'abe5276f-b9ea-4f48-ae04-3f001b04124f'	System	18 Oct 2020 21:45:27
User entered 'No (N)'	System	18 Oct 2020 21:45:27

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:45:04', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'abe5276f-b9ea-4f48-ae04-3f001b04124f'	System	18 Oct 2020 21:45:27
User entered 'None (1)'	System	18 Oct 2020 21:45:27

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:45:22', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'abe5276f-b9ea-4f48-ae04-3f001b04124f'	System	18 Oct 2020 21:45:27
User entered '18 Oct 2020 17:45'	System	18 Oct 2020 21:45:27

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 5'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:12', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a1460087-e3e1-407b-85f4-02042dd8bddf'	System	20 Oct 2020 04:29:28
User entered 'None (1)'	System	20 Oct 2020 04:29:28

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:15', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a1460087-e3e1-407b-85f4-02042dd8bddf'	System	20 Oct 2020 04:29:28
User entered 'No (N)'	System	20 Oct 2020 04:29:28

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:18', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a1460087-e3e1-407b-85f4-02042dd8bddf'	System	20 Oct 2020 04:29:28
User entered 'No (N)'	System	20 Oct 2020 04:29:28

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:22', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a1460087-e3e1-407b-85f4-02042dd8bddf'	System	20 Oct 2020 04:29:28
User entered 'None (1)'	System	20 Oct 2020 04:29:28

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:24', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a1460087-e3e1-407b-85f4-02042dd8bddf'	System	20 Oct 2020 04:29:28
User entered '20 Oct 2020 00:29'	System	20 Oct 2020 04:29:28

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 6'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:00', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'da2eaea7-ff17-402d-8909-cf6d338e4a4d'	System	21 Oct 2020 00:24:25
User entered 'None (1)'	System	21 Oct 2020 00:24:25

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:03', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'da2eaea7-ff17-402d-8909-cf6d338e4a4d'	System	21 Oct 2020 00:24:25
User entered 'No (N)'	System	21 Oct 2020 00:24:25

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:08', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'da2eaea7-ff17-402d-8909-cf6d338e4a4d'	System	21 Oct 2020 00:24:25
User entered 'No (N)'	System	21 Oct 2020 00:24:25

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:16', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'da2eaea7-ff17-402d-8909-cf6d338e4a4d'	System	21 Oct 2020 00:24:25
User entered 'None (1)'	System	21 Oct 2020 00:24:25

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:18', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'da2eaea7-ff17-402d-8909-cf6d338e4a4d'	System	21 Oct 2020 00:24:25
User entered '20 Oct 2020 20:24'	System	21 Oct 2020 00:24:25

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 7'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:21:47', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '49e97105-2490-4c59-bccf-ffaf3ea46724'	System	22 Oct 2020 02:22:06
User entered 'None (1)'	System	22 Oct 2020 02:22:06

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:21:50', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '49e97105-2490-4c59-bccf-ffaf3ea46724'	System	22 Oct 2020 02:22:06
User entered 'No (N)'	System	22 Oct 2020 02:22:06

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:21:55', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '49e97105-2490-4c59-bccf-ffaf3ea46724'	System	22 Oct 2020 02:22:06
User entered 'No (N)'	System	22 Oct 2020 02:22:06

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:21:59', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '49e97105-2490-4c59-bccf-ffaf3ea46724'	System	22 Oct 2020 02:22:06
User entered 'None (1)'	System	22 Oct 2020 02:22:06

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:22:01', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '49e97105-2490-4c59-bccf-ffaf3ea46724'	System	22 Oct 2020 02:22:06
User entered '21 Oct 2020 22:22'	System	22 Oct 2020 02:22:06

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:28', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7b19d3fb-36dd-4309-8135-000cdb6b7c7e'	System	15 Oct 2020 15:37:10
User entered 'None (0)'	System	15 Oct 2020 15:37:10

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:34', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7b19d3fb-36dd-4309-8135-000cdb6b7c7e'	System	15 Oct 2020 15:37:10
User entered 'None (0)'	System	15 Oct 2020 15:37:10

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:37', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7b19d3fb-36dd-4309-8135-000cdb6b7c7e'	System	15 Oct 2020 15:37:10
User entered 'None (0)'	System	15 Oct 2020 15:37:10

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:41', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7b19d3fb-36dd-4309-8135-000cdb6b7c7e'	System	15 Oct 2020 15:37:10
User entered 'None (0)'	System	15 Oct 2020 15:37:10

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:47', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7b19d3fb-36dd-4309-8135-000cdb6b7c7e'	System	15 Oct 2020 15:37:10
User entered 'None (0)'	System	15 Oct 2020 15:37:10

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:36:51', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7b19d3fb-36dd-4309-8135-000cdb6b7c7e'	System	15 Oct 2020 15:37:10
User entered 'None (0)'	System	15 Oct 2020 15:37:10

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:37:00', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7b19d3fb-36dd-4309-8135-000cdb6b7c7e'	System	15 Oct 2020 15:37:10
User entered 'No (N)'	System	15 Oct 2020 15:37:10

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T11:37:04', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7b19d3fb-36dd-4309-8135-000cdb6b7c7e'	System	15 Oct 2020 15:37:10
User entered '15 Oct 2020 11:37'	System	15 Oct 2020 15:37:10

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Oct 2020 11:18'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Oct 2020 13:48'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:14:24', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '94e5d772-2ee0-4c39-8559-e6d9e735aac5'	System	16 Oct 2020 00:15:24
User entered 'None (0)'	System	16 Oct 2020 00:15:24

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:14:31', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '94e5d772-2ee0-4c39-8559-e6d9e735aac5'	System	16 Oct 2020 00:15:24
User entered 'None (0)'	System	16 Oct 2020 00:15:24

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:14:36', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '94e5d772-2ee0-4c39-8559-e6d9e735aac5'	System	16 Oct 2020 00:15:24
User entered 'None (0)'	System	16 Oct 2020 00:15:24

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:14:44', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '94e5d772-2ee0-4c39-8559-e6d9e735aac5'	System	16 Oct 2020 00:15:24
User entered 'None (0)'	System	16 Oct 2020 00:15:24

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:14:51', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '94e5d772-2ee0-4c39-8559-e6d9e735aac5'	System	16 Oct 2020 00:15:24
User entered 'None (0)'	System	16 Oct 2020 00:15:24

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:15:02', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '94e5d772-2ee0-4c39-8559-e6d9e735aac5'	System	16 Oct 2020 00:15:24
User entered 'None (0)'	System	16 Oct 2020 00:15:24

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:15:15', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '94e5d772-2ee0-4c39-8559-e6d9e735aac5'	System	16 Oct 2020 00:15:24
User entered 'No (N)'	System	16 Oct 2020 00:15:24

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-15T20:15:20', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '94e5d772-2ee0-4c39-8559-e6d9e735aac5'	System	16 Oct 2020 00:15:24
User entered '15 Oct 2020 20:15'	System	16 Oct 2020 00:15:24

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Oct 2020 14:43'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 2'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:38', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f8a91fc5-b826-4cf1-ad4d-8f2d2b582736'	System	16 Oct 2020 18:03:02
User entered 'None (0)'	System	16 Oct 2020 18:03:02

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:41', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f8a91fc5-b826-4cf1-ad4d-8f2d2b582736'	System	16 Oct 2020 18:03:02
User entered 'None (0)'	System	16 Oct 2020 18:03:02

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:45', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f8a91fc5-b826-4cf1-ad4d-8f2d2b582736'	System	16 Oct 2020 18:03:02
User entered 'None (0)'	System	16 Oct 2020 18:03:02

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:48', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f8a91fc5-b826-4cf1-ad4d-8f2d2b582736'	System	16 Oct 2020 18:03:02
User entered 'None (0)'	System	16 Oct 2020 18:03:02

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:50', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f8a91fc5-b826-4cf1-ad4d-8f2d2b582736'	System	16 Oct 2020 18:03:02
User entered 'None (0)'	System	16 Oct 2020 18:03:02

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:53', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f8a91fc5-b826-4cf1-ad4d-8f2d2b582736'	System	16 Oct 2020 18:03:02
User entered 'None (0)'	System	16 Oct 2020 18:03:02

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:56', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f8a91fc5-b826-4cf1-ad4d-8f2d2b582736'	System	16 Oct 2020 18:03:02
User entered 'No (N)'	System	16 Oct 2020 18:03:02

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-16T14:02:59', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f8a91fc5-b826-4cf1-ad4d-8f2d2b582736'	System	16 Oct 2020 18:03:02
User entered '16 Oct 2020 14:02'	System	16 Oct 2020 18:03:02

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 3'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:03:57', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '91c1b493-9acd-478f-a17b-4269ee0f0c65'	System	18 Oct 2020 01:04:39
User entered 'None (0)'	System	18 Oct 2020 01:04:39

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:04:03', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '91c1b493-9acd-478f-a17b-4269ee0f0c65'	System	18 Oct 2020 01:04:39
User entered 'None (0)'	System	18 Oct 2020 01:04:39

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:04:06', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '91c1b493-9acd-478f-a17b-4269ee0f0c65'	System	18 Oct 2020 01:04:39
User entered 'None (0)'	System	18 Oct 2020 01:04:39

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:04:10', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '91c1b493-9acd-478f-a17b-4269ee0f0c65'	System	18 Oct 2020 01:04:39
User entered 'None (0)'	System	18 Oct 2020 01:04:39

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:04:19', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '91c1b493-9acd-478f-a17b-4269ee0f0c65'	System	18 Oct 2020 01:04:39
User entered 'None (0)'	System	18 Oct 2020 01:04:39

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:04:22', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '91c1b493-9acd-478f-a17b-4269ee0f0c65'	System	18 Oct 2020 01:04:39
User entered 'None (0)'	System	18 Oct 2020 01:04:39

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:04:31', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '91c1b493-9acd-478f-a17b-4269ee0f0c65'	System	18 Oct 2020 01:04:39
User entered 'No (N)'	System	18 Oct 2020 01:04:39

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-17T21:04:34', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '91c1b493-9acd-478f-a17b-4269ee0f0c65'	System	18 Oct 2020 01:04:39
User entered '17 Oct 2020 21:04'	System	18 Oct 2020 01:04:39

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 4'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:45:28', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '878d3b45-2f9a-4d2e-8c51-ae35af10f857'	System	18 Oct 2020 21:46:05
User entered 'None (0)'	System	18 Oct 2020 21:46:05

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:45:31', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '878d3b45-2f9a-4d2e-8c51-ae35af10f857'	System	18 Oct 2020 21:46:05
User entered 'None (0)'	System	18 Oct 2020 21:46:05

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:45:37', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '878d3b45-2f9a-4d2e-8c51-ae35af10f857'	System	18 Oct 2020 21:46:05
User entered 'None (0)'	System	18 Oct 2020 21:46:05

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:45:44', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '878d3b45-2f9a-4d2e-8c51-ae35af10f857'	System	18 Oct 2020 21:46:05
User entered 'None (0)'	System	18 Oct 2020 21:46:05

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:45:51', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '878d3b45-2f9a-4d2e-8c51-ae35af10f857'	System	18 Oct 2020 21:46:05
User entered 'None (0)'	System	18 Oct 2020 21:46:05

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:45:53', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '878d3b45-2f9a-4d2e-8c51-ae35af10f857'	System	18 Oct 2020 21:46:05
User entered 'None (0)'	System	18 Oct 2020 21:46:05

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:45:58', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '878d3b45-2f9a-4d2e-8c51-ae35af10f857'	System	18 Oct 2020 21:46:05
User entered 'No (N)'	System	18 Oct 2020 21:46:05

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-18T17:46:04', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '878d3b45-2f9a-4d2e-8c51-ae35af10f857'	System	18 Oct 2020 21:46:05
User entered '18 Oct 2020 17:46'	System	18 Oct 2020 21:46:05

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 5'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:31', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6f8473a6-590a-42e2-a9e0-88ffdb479503'	System	20 Oct 2020 04:30:03
User entered 'None (0)'	System	20 Oct 2020 04:30:03

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:35', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6f8473a6-590a-42e2-a9e0-88ffdb479503'	System	20 Oct 2020 04:30:03
User entered 'None (0)'	System	20 Oct 2020 04:30:03

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:39', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6f8473a6-590a-42e2-a9e0-88ffdb479503'	System	20 Oct 2020 04:30:03
User entered 'None (0)'	System	20 Oct 2020 04:30:03

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:44', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6f8473a6-590a-42e2-a9e0-88ffdb479503'	System	20 Oct 2020 04:30:03
User entered 'None (0)'	System	20 Oct 2020 04:30:03

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:48', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6f8473a6-590a-42e2-a9e0-88ffdb479503'	System	20 Oct 2020 04:30:03
User entered 'None (0)'	System	20 Oct 2020 04:30:03

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:51', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6f8473a6-590a-42e2-a9e0-88ffdb479503'	System	20 Oct 2020 04:30:03
User entered 'None (0)'	System	20 Oct 2020 04:30:03

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:55', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6f8473a6-590a-42e2-a9e0-88ffdb479503'	System	20 Oct 2020 04:30:03
User entered 'No (N)'	System	20 Oct 2020 04:30:03

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T00:29:57', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6f8473a6-590a-42e2-a9e0-88ffdb479503'	System	20 Oct 2020 04:30:03
User entered '20 Oct 2020 00:29'	System	20 Oct 2020 04:30:03

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 6'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:25', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5ef6ba39-28f6-4e46-a547-8c0b5aa3c4e8'	System	21 Oct 2020 00:25:06
User entered 'None (0)'	System	21 Oct 2020 00:25:06

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:28', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5ef6ba39-28f6-4e46-a547-8c0b5aa3c4e8'	System	21 Oct 2020 00:25:06
User entered 'None (0)'	System	21 Oct 2020 00:25:06

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:39', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5ef6ba39-28f6-4e46-a547-8c0b5aa3c4e8'	System	21 Oct 2020 00:25:06
User entered 'None (0)'	System	21 Oct 2020 00:25:06

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:43', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5ef6ba39-28f6-4e46-a547-8c0b5aa3c4e8'	System	21 Oct 2020 00:25:06
User entered 'None (0)'	System	21 Oct 2020 00:25:06

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:46', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5ef6ba39-28f6-4e46-a547-8c0b5aa3c4e8'	System	21 Oct 2020 00:25:06
User entered 'None (0)'	System	21 Oct 2020 00:25:06

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:50', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5ef6ba39-28f6-4e46-a547-8c0b5aa3c4e8'	System	21 Oct 2020 00:25:06
User entered 'None (0)'	System	21 Oct 2020 00:25:06

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:54', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5ef6ba39-28f6-4e46-a547-8c0b5aa3c4e8'	System	21 Oct 2020 00:25:06
User entered 'No (N)'	System	21 Oct 2020 00:25:06

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-20T20:24:57', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5ef6ba39-28f6-4e46-a547-8c0b5aa3c4e8'	System	21 Oct 2020 00:25:06
User entered '20 Oct 2020 20:24'	System	21 Oct 2020 00:25:06

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	15 Oct 2020 15:13:42
User entered 'Day 7'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:22:17', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '102bc3de-1a67-4d3f-9719-a1347208d49f'	System	22 Oct 2020 02:22:50
User entered 'None (0)'	System	22 Oct 2020 02:22:50

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:22:20', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '102bc3de-1a67-4d3f-9719-a1347208d49f'	System	22 Oct 2020 02:22:50
User entered 'None (0)'	System	22 Oct 2020 02:22:50

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:22:25', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '102bc3de-1a67-4d3f-9719-a1347208d49f'	System	22 Oct 2020 02:22:50
User entered 'None (0)'	System	22 Oct 2020 02:22:50

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:22:29', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '102bc3de-1a67-4d3f-9719-a1347208d49f'	System	22 Oct 2020 02:22:50
User entered 'None (0)'	System	22 Oct 2020 02:22:50

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:22:32', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '102bc3de-1a67-4d3f-9719-a1347208d49f'	System	22 Oct 2020 02:22:50
User entered 'None (0)'	System	22 Oct 2020 02:22:50

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:22:35', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '102bc3de-1a67-4d3f-9719-a1347208d49f'	System	22 Oct 2020 02:22:50
User entered 'None (0)'	System	22 Oct 2020 02:22:50

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:22:41', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '102bc3de-1a67-4d3f-9719-a1347208d49f'	System	22 Oct 2020 02:22:50
User entered 'No (N)'	System	22 Oct 2020 02:22:50

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-10-21T22:22:43', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '102bc3de-1a67-4d3f-9719-a1347208d49f'	System	22 Oct 2020 02:22:50
User entered '21 Oct 2020 22:22'	System	22 Oct 2020 02:22:50

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 15:13:42

US3712174

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 15:13:42

US3712174

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:32:59

US3712174

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:32:59

US3712174

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:32:59

US3712174

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:32:59

US3712174

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:33:46

US3712174

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'I'	System	27 Oct 2020 18:33:46

US3712174

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:53

US3712174

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:53

US3712174

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:53

US3712174

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:53

US3712174

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:54

US3712174

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:30:54
User entered 'I'	System	02 Nov 2020 14:43:54

US3712174

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:21:54

US3712174

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:21:54

US3712174

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:21:54

US3712174

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:21:54

US3712174

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:21:56

US3712174

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'I'	System	10 Nov 2020 13:21:56

US3712174

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:15

US3712174

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:15

US3712174

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:15

US3712174

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'VISIT2'	System	11 Nov 2020 14:55:15

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '08:35'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered '11 Nov 2020 08:35'	System	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '96'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'bpm'	System	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'breaths/min'	System	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '128'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'mmHg'	System	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '87'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'mmHg'	System	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '10:19'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered '11 Nov 2020 10:19'	System	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '71'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'bpm'	System	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'breaths/min'	System	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '117'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'mmHg'	System	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '75'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'mmHg'	System	11 Nov 2020 21:23:10

US3712174

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:32

US3712174

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:32

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:56:23

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:56:23

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

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)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:56:23

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'MRNA-1273 OR PLACEBO'	System	11 Nov 2020 14:56:23

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:56:23

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '09:44'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:56:23

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered '11 Nov 2020 09:44'	System	11 Nov 2020 14:56:23

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:56:23

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'ONCE'	System	11 Nov 2020 14:56:23

US3712174

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'INTRAMUSCULAR'	System	11 Nov 2020 14:56:23

US3712174

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:47

US3712174

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:47

US3712174

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '08:52'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:47

US3712174

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered '11 Nov 2020 08:52'	System	11 Nov 2020 14:55:47

US3712174

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:29:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:56

US3712174

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Nov 2020 14:55:56

US3712174

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:56

US3712174

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '08:55'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:56

US3712174

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered '11 Nov 2020 08:55'	System	11 Nov 2020 14:55:56

US3712174

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Nov 2020 14:55:56

US3712174

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:48:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:09:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 19:09:34
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:56

US3712174

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:48:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:09:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 19:09:34
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '08:55'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:56

US3712174

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered empty.	System	12 Mar 2021 19:09:34
User entered '11 Nov 2020 08:55'	System	11 Nov 2020 14:55:56

US3712174

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:56:01

US3712174

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'I'	System	11 Nov 2020 14:56:01

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:29:37', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7f4d00fa-4989-43a7-8054-902f566bae88'	System	11 Nov 2020 15:29:59
User entered 'Yes (Y)'	System	11 Nov 2020 15:29:59

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:29:48', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7f4d00fa-4989-43a7-8054-902f566bae88'	System	11 Nov 2020 15:29:59
User entered '97.9'	System	11 Nov 2020 15:29:59

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:29:53', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7f4d00fa-4989-43a7-8054-902f566bae88'	System	11 Nov 2020 15:29:59
User entered 'No (N)'	System	11 Nov 2020 15:29:59

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:29:55', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7f4d00fa-4989-43a7-8054-902f566bae88'	System	11 Nov 2020 15:29:59
User entered '11 Nov 2020 10:29'	System	11 Nov 2020 15:29:59

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '11 Nov 2020 10:04'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '11 Nov 2020 12:34'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:52:32', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '565e33fa-be60-44ad-8596-79f8da264bf3'	System	12 Nov 2020 01:52:49
User entered 'Yes (Y)'	System	12 Nov 2020 01:52:49

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:52:37', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '565e33fa-be60-44ad-8596-79f8da264bf3'	System	12 Nov 2020 01:52:49
User entered '98.3'	System	12 Nov 2020 01:52:49

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:52:42', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '565e33fa-be60-44ad-8596-79f8da264bf3'	System	12 Nov 2020 01:52:49
User entered 'No (N)'	System	12 Nov 2020 01:52:49

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:52:46', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '565e33fa-be60-44ad-8596-79f8da264bf3'	System	12 Nov 2020 01:52:49
User entered '11 Nov 2020 20:52'	System	12 Nov 2020 01:52:49

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '11 Nov 2020 13:29'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 2'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:38:47', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f9b2d873-cd41-4122-8855-5b61338b30a8'	System	13 Nov 2020 01:39:12
User entered 'Yes (Y)'	System	13 Nov 2020 01:39:12

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:00', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f9b2d873-cd41-4122-8855-5b61338b30a8' User entered '97.7'	System	13 Nov 2020 01:39:12
	System	13 Nov 2020 01:39:12

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:04', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f9b2d873-cd41-4122-8855-5b61338b30a8'	System	13 Nov 2020 01:39:12
User entered 'No (N)'	System	13 Nov 2020 01:39:12

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:07', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f9b2d873-cd41-4122-8855-5b61338b30a8'	System	13 Nov 2020 01:39:12
User entered '12 Nov 2020 20:39'	System	13 Nov 2020 01:39:12

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 3'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:22:52', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f852f0e1-fa42-4623-ac3b-3a2a9f3e5d7b'	System	14 Nov 2020 03:23:11
User entered 'Yes (Y)'	System	14 Nov 2020 03:23:11

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:22:59', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f852f0e1-fa42-4623-ac3b-3a2a9f3e5d7b'	System	14 Nov 2020 03:23:11
User entered '98.3'	System	14 Nov 2020 03:23:11

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:23:03', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f852f0e1-fa42-4623-ac3b-3a2a9f3e5d7b'	System	14 Nov 2020 03:23:11
User entered 'No (N)'	System	14 Nov 2020 03:23:11

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:23:05', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f852f0e1-fa42-4623-ac3b-3a2a9f3e5d7b'	System	14 Nov 2020 03:23:11
User entered '13 Nov 2020 22:23'	System	14 Nov 2020 03:23:11

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 4'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:22:40', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '21358c1c-1596-4b3c-a151-8ecf58236f2d'	System	15 Nov 2020 03:23:11
User entered 'Yes (Y)'	System	15 Nov 2020 03:23:11

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:22:47', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '21358c1c-1596-4b3c-a151-8ecf58236f2d'	System	15 Nov 2020 03:23:11
User entered '98.2'	System	15 Nov 2020 03:23:11

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:22:52', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '21358c1c-1596-4b3c-a151-8ecf58236f2d'	System	15 Nov 2020 03:23:11
User entered 'No (N)'	System	15 Nov 2020 03:23:11

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:23:07', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '21358c1c-1596-4b3c-a151-8ecf58236f2d'	System	15 Nov 2020 03:23:11
User entered '14 Nov 2020 22:23'	System	15 Nov 2020 03:23:11

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 5'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:02:37', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5a6c61be-69bf-4e00-9349-feae4037b4b5'	System	16 Nov 2020 01:02:57
User entered 'Yes (Y)'	System	16 Nov 2020 01:02:57

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:02:41', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5a6c61be-69bf-4e00-9349-feae4037b4b5' User entered '98.2'	System	16 Nov 2020 01:02:57
	System	16 Nov 2020 01:02:57

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:02:48', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5a6c61be-69bf-4e00-9349-feae4037b4b5'	System	16 Nov 2020 01:02:57
User entered 'No (N)'	System	16 Nov 2020 01:02:57

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:02:53', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5a6c61be-69bf-4e00-9349-feae4037b4b5'	System	16 Nov 2020 01:02:57
User entered '15 Nov 2020 20:02'	System	16 Nov 2020 01:02:57

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 6'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:47:24', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'd09ad474-84de-45f3-b260-372c94db08c4'	System	17 Nov 2020 10:47:41
User entered 'Yes (Y)'	System	17 Nov 2020 10:47:41

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:47:32', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'd09ad474-84de-45f3-b260-372c94db08c4'	System	17 Nov 2020 10:47:41
User entered '98.2'	System	17 Nov 2020 10:47:41

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:47:35', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'd09ad474-84de-45f3-b260-372c94db08c4'	System	17 Nov 2020 10:47:41
User entered 'No (N)'	System	17 Nov 2020 10:47:41

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:47:37', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'd09ad474-84de-45f3-b260-372c94db08c4'	System	17 Nov 2020 10:47:41
User entered '17 Nov 2020 05:47'	System	17 Nov 2020 10:47:41

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 7'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:11', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '40cb970f-1828-4e50-ab14-685dcabed43b'	System	18 Nov 2020 00:20:26
User entered 'Yes (Y)'	System	18 Nov 2020 00:20:26

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:17', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '40cb970f-1828-4e50-ab14-685dcabed43b'	System	18 Nov 2020 00:20:26
User entered '97.5'	System	18 Nov 2020 00:20:26

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:21', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '40cb970f-1828-4e50-ab14-685dcabed43b'	System	18 Nov 2020 00:20:26
User entered 'No (N)'	System	18 Nov 2020 00:20:26

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:23', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '40cb970f-1828-4e50-ab14-685dcabed43b'	System	18 Nov 2020 00:20:26
User entered '17 Nov 2020 19:20'	System	18 Nov 2020 00:20:26

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:04', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '53a879de-d249-4f8f-8314-f2870ac99280'	System	11 Nov 2020 15:31:18
User entered 'None (1)'	System	11 Nov 2020 15:31:18

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:07', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '53a879de-d249-4f8f-8314-f2870ac99280'	System	11 Nov 2020 15:31:18
User entered 'No (N)'	System	11 Nov 2020 15:31:18

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:09', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '53a879de-d249-4f8f-8314-f2870ac99280'	System	11 Nov 2020 15:31:18
User entered 'No (N)'	System	11 Nov 2020 15:31:18

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:12', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '53a879de-d249-4f8f-8314-f2870ac99280'	System	11 Nov 2020 15:31:18
User entered 'None (1)'	System	11 Nov 2020 15:31:18

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:15', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '53a879de-d249-4f8f-8314-f2870ac99280'	System	11 Nov 2020 15:31:18
User entered '11 Nov 2020 10:31'	System	11 Nov 2020 15:31:18

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '11 Nov 2020 10:04'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '11 Nov 2020 12:34'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:52:52', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '107d8857-d321-48fc-b666-b2f92d544ee8'	System	12 Nov 2020 01:53:14
User entered 'None (1)'	System	12 Nov 2020 01:53:14

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:52:56', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '107d8857-d321-48fc-b666-b2f92d544ee8'	System	12 Nov 2020 01:53:14
User entered 'No (N)'	System	12 Nov 2020 01:53:14

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:00', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '107d8857-d321-48fc-b666-b2f92d544ee8'	System	12 Nov 2020 01:53:14
User entered 'No (N)'	System	12 Nov 2020 01:53:14

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:04', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '107d8857-d321-48fc-b666-b2f92d544ee8'	System	12 Nov 2020 01:53:14
User entered 'None (1)'	System	12 Nov 2020 01:53:14

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:10', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '107d8857-d321-48fc-b666-b2f92d544ee8'	System	12 Nov 2020 01:53:14
User entered '11 Nov 2020 20:53'	System	12 Nov 2020 01:53:14

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '11 Nov 2020 13:29'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 2'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:11', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a24664ae-37b7-4c00-b03a-730ae585f662'	System	13 Nov 2020 01:39:31
User entered 'None (1)'	System	13 Nov 2020 01:39:31

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:14', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a24664ae-37b7-4c00-b03a-730ae585f662'	System	13 Nov 2020 01:39:31
User entered 'No (N)'	System	13 Nov 2020 01:39:31

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:19', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a24664ae-37b7-4c00-b03a-730ae585f662'	System	13 Nov 2020 01:39:31
User entered 'No (N)'	System	13 Nov 2020 01:39:31

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:22', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a24664ae-37b7-4c00-b03a-730ae585f662'	System	13 Nov 2020 01:39:31
User entered 'None (1)'	System	13 Nov 2020 01:39:31

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:25', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a24664ae-37b7-4c00-b03a-730ae585f662'	System	13 Nov 2020 01:39:31
User entered '12 Nov 2020 20:39'	System	13 Nov 2020 01:39:31

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 3'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:23:12', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5b587f06-5094-4412-806e-1bd003176f4d'	System	14 Nov 2020 03:24:01
User entered 'None (1)'	System	14 Nov 2020 03:24:01

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:23:15', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5b587f06-5094-4412-806e-1bd003176f4d'	System	14 Nov 2020 03:24:01
User entered 'No (N)'	System	14 Nov 2020 03:24:01

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:23:38', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5b587f06-5094-4412-806e-1bd003176f4d'	System	14 Nov 2020 03:24:01
User entered 'No (N)'	System	14 Nov 2020 03:24:01

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:23:51', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5b587f06-5094-4412-806e-1bd003176f4d'	System	14 Nov 2020 03:24:01
User entered 'None (1)'	System	14 Nov 2020 03:24:01

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:23:55', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '5b587f06-5094-4412-806e-1bd003176f4d'	System	14 Nov 2020 03:24:01
User entered '13 Nov 2020 22:23'	System	14 Nov 2020 03:24:01

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 4'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:23:18', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6299cb54-2da9-498a-b566-cbef5d0a3e6d'	System	15 Nov 2020 03:23:50
User entered 'None (1)'	System	15 Nov 2020 03:23:50

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:23:22', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6299cb54-2da9-498a-b566-cbef5d0a3e6d'	System	15 Nov 2020 03:23:50
User entered 'No (N)'	System	15 Nov 2020 03:23:50

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:23:30', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6299cb54-2da9-498a-b566-cbef5d0a3e6d'	System	15 Nov 2020 03:23:50
User entered 'No (N)'	System	15 Nov 2020 03:23:50

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:23:42', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6299cb54-2da9-498a-b566-cbef5d0a3e6d'	System	15 Nov 2020 03:23:50
User entered 'None (1)'	System	15 Nov 2020 03:23:50

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:23:47', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '6299cb54-2da9-498a-b566-cbef5d0a3e6d'	System	15 Nov 2020 03:23:50
User entered '14 Nov 2020 22:23'	System	15 Nov 2020 03:23:50

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 5'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:02:58', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '1319c942-ba36-4553-a833-2a69d2dc6aeb'	System	16 Nov 2020 01:03:13
User entered 'None (1)'	System	16 Nov 2020 01:03:13

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:00', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '1319c942-ba36-4553-a833-2a69d2dc6aeb'	System	16 Nov 2020 01:03:13
User entered 'No (N)'	System	16 Nov 2020 01:03:13

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:03', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '1319c942-ba36-4553-a833-2a69d2dc6aeb'	System	16 Nov 2020 01:03:13
User entered 'No (N)'	System	16 Nov 2020 01:03:13

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:06', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '1319c942-ba36-4553-a833-2a69d2dc6aeb'	System	16 Nov 2020 01:03:13
User entered 'None (1)'	System	16 Nov 2020 01:03:13

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:10', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '1319c942-ba36-4553-a833-2a69d2dc6aeb'	System	16 Nov 2020 01:03:13
User entered '15 Nov 2020 20:03'	System	16 Nov 2020 01:03:13

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 6'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:47:43', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'e0e6b91a-ab99-4bce-8c12-010906c38fad'	System	17 Nov 2020 10:47:58
User entered 'None (1)'	System	17 Nov 2020 10:47:58

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:47:46', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'e0e6b91a-ab99-4bce-8c12-010906c38fad'	System	17 Nov 2020 10:47:58
User entered 'No (N)'	System	17 Nov 2020 10:47:58

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:47:48', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'e0e6b91a-ab99-4bce-8c12-010906c38fad'	System	17 Nov 2020 10:47:58
User entered 'No (N)'	System	17 Nov 2020 10:47:58

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:47:51', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'e0e6b91a-ab99-4bce-8c12-010906c38fad'	System	17 Nov 2020 10:47:58
User entered 'None (1)'	System	17 Nov 2020 10:47:58

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:47:54', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'e0e6b91a-ab99-4bce-8c12-010906c38fad'	System	17 Nov 2020 10:47:58
User entered '17 Nov 2020 05:47'	System	17 Nov 2020 10:47:58

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 7'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:32', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a51c629d-a165-4b97-92a2-feb52707e9e3'	System	18 Nov 2020 00:20:47
User entered 'None (1)'	System	18 Nov 2020 00:20:47

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:34', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a51c629d-a165-4b97-92a2-feb52707e9e3'	System	18 Nov 2020 00:20:47
User entered 'No (N)'	System	18 Nov 2020 00:20:47

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:37', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a51c629d-a165-4b97-92a2-feb52707e9e3'	System	18 Nov 2020 00:20:47
User entered 'No (N)'	System	18 Nov 2020 00:20:47

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:41', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a51c629d-a165-4b97-92a2-feb52707e9e3'	System	18 Nov 2020 00:20:47
User entered 'None (1)'	System	18 Nov 2020 00:20:47

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:43', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'a51c629d-a165-4b97-92a2-feb52707e9e3'	System	18 Nov 2020 00:20:47
User entered '17 Nov 2020 19:20'	System	18 Nov 2020 00:20:47

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:25', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '39ad16f9-0a8b-45af-ac04-54e5c3d79f67'	System	11 Nov 2020 15:31:45
User entered 'None (0)'	System	11 Nov 2020 15:31:45

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:27', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '39ad16f9-0a8b-45af-ac04-54e5c3d79f67'	System	11 Nov 2020 15:31:45
User entered 'None (0)'	System	11 Nov 2020 15:31:45

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:30', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '39ad16f9-0a8b-45af-ac04-54e5c3d79f67'	System	11 Nov 2020 15:31:45
User entered 'None (0)'	System	11 Nov 2020 15:31:45

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:33', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '39ad16f9-0a8b-45af-ac04-54e5c3d79f67'	System	11 Nov 2020 15:31:45
User entered 'None (0)'	System	11 Nov 2020 15:31:45

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:35', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '39ad16f9-0a8b-45af-ac04-54e5c3d79f67'	System	11 Nov 2020 15:31:45
User entered 'None (0)'	System	11 Nov 2020 15:31:45

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:38', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '39ad16f9-0a8b-45af-ac04-54e5c3d79f67'	System	11 Nov 2020 15:31:45
User entered 'None (0)'	System	11 Nov 2020 15:31:45

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:40', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '39ad16f9-0a8b-45af-ac04-54e5c3d79f67'	System	11 Nov 2020 15:31:45
User entered 'No (N)'	System	11 Nov 2020 15:31:45

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T10:31:42', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '39ad16f9-0a8b-45af-ac04-54e5c3d79f67'	System	11 Nov 2020 15:31:45
User entered '11 Nov 2020 10:31'	System	11 Nov 2020 15:31:45

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '11 Nov 2020 10:04'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '11 Nov 2020 12:34'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:23', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'c2d80314-72d7-4da7-b56c-94d66a6c25dd'	System	12 Nov 2020 01:53:51
User entered 'None (0)'	System	12 Nov 2020 01:53:51

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:27', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'c2d80314-72d7-4da7-b56c-94d66a6c25dd'	System	12 Nov 2020 01:53:51
User entered 'None (0)'	System	12 Nov 2020 01:53:51

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:30', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'c2d80314-72d7-4da7-b56c-94d66a6c25dd'	System	12 Nov 2020 01:53:51
User entered 'None (0)'	System	12 Nov 2020 01:53:51

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:33', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'c2d80314-72d7-4da7-b56c-94d66a6c25dd'	System	12 Nov 2020 01:53:51
User entered 'None (0)'	System	12 Nov 2020 01:53:51

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:35', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'c2d80314-72d7-4da7-b56c-94d66a6c25dd'	System	12 Nov 2020 01:53:51
User entered 'None (0)'	System	12 Nov 2020 01:53:51

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:38', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'c2d80314-72d7-4da7-b56c-94d66a6c25dd'	System	12 Nov 2020 01:53:51
User entered 'None (0)'	System	12 Nov 2020 01:53:51

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:43', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'c2d80314-72d7-4da7-b56c-94d66a6c25dd'	System	12 Nov 2020 01:53:51
User entered 'No (N)'	System	12 Nov 2020 01:53:51

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-11T20:53:45', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'c2d80314-72d7-4da7-b56c-94d66a6c25dd'	System	12 Nov 2020 01:53:51
User entered '11 Nov 2020 20:53'	System	12 Nov 2020 01:53:51

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '11 Nov 2020 13:29'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 2'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:29', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f00d9416-978c-4ae7-ab16-5e2b7ab7df7f'	System	13 Nov 2020 01:39:53
User entered 'None (0)'	System	13 Nov 2020 01:39:53

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:32', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f00d9416-978c-4ae7-ab16-5e2b7ab7df7f'	System	13 Nov 2020 01:39:53
User entered 'None (0)'	System	13 Nov 2020 01:39:53

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:35', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f00d9416-978c-4ae7-ab16-5e2b7ab7df7f'	System	13 Nov 2020 01:39:53
User entered 'None (0)'	System	13 Nov 2020 01:39:53

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:38', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f00d9416-978c-4ae7-ab16-5e2b7ab7df7f'	System	13 Nov 2020 01:39:53
User entered 'None (0)'	System	13 Nov 2020 01:39:53

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:41', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f00d9416-978c-4ae7-ab16-5e2b7ab7df7f'	System	13 Nov 2020 01:39:53
User entered 'None (0)'	System	13 Nov 2020 01:39:53

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:43', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f00d9416-978c-4ae7-ab16-5e2b7ab7df7f'	System	13 Nov 2020 01:39:53
User entered 'None (0)'	System	13 Nov 2020 01:39:53

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:47', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f00d9416-978c-4ae7-ab16-5e2b7ab7df7f'	System	13 Nov 2020 01:39:53
User entered 'No (N)'	System	13 Nov 2020 01:39:53

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-12T20:39:50', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'f00d9416-978c-4ae7-ab16-5e2b7ab7df7f'	System	13 Nov 2020 01:39:53
User entered '12 Nov 2020 20:39'	System	13 Nov 2020 01:39:53

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 3'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:24:14', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7ba5003d-5ad2-4fb8-840f-960dc477207a'	System	14 Nov 2020 03:24:40
User entered 'None (0)'	System	14 Nov 2020 03:24:40

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:24:16', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7ba5003d-5ad2-4fb8-840f-960dc477207a'	System	14 Nov 2020 03:24:40
User entered 'None (0)'	System	14 Nov 2020 03:24:40

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:24:20', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7ba5003d-5ad2-4fb8-840f-960dc477207a'	System	14 Nov 2020 03:24:40
User entered 'None (0)'	System	14 Nov 2020 03:24:40

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:24:23', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7ba5003d-5ad2-4fb8-840f-960dc477207a'	System	14 Nov 2020 03:24:40
User entered 'None (0)'	System	14 Nov 2020 03:24:40

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:24:26', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7ba5003d-5ad2-4fb8-840f-960dc477207a'	System	14 Nov 2020 03:24:40
User entered 'None (0)'	System	14 Nov 2020 03:24:40

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:24:28', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7ba5003d-5ad2-4fb8-840f-960dc477207a'	System	14 Nov 2020 03:24:40
User entered 'None (0)'	System	14 Nov 2020 03:24:40

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:24:32', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7ba5003d-5ad2-4fb8-840f-960dc477207a'	System	14 Nov 2020 03:24:40
User entered 'No (N)'	System	14 Nov 2020 03:24:40

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-13T22:24:35', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '7ba5003d-5ad2-4fb8-840f-960dc477207a'	System	14 Nov 2020 03:24:40
User entered '13 Nov 2020 22:24'	System	14 Nov 2020 03:24:40

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 4'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:23:54', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '161bfae7-2abb-4c24-802b-15a7e2b5c5a3'	System	15 Nov 2020 03:24:38
User entered 'None (0)'	System	15 Nov 2020 03:24:38

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:23:58', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '161bfae7-2abb-4c24-802b-15a7e2b5c5a3'	System	15 Nov 2020 03:24:38
User entered 'None (0)'	System	15 Nov 2020 03:24:38

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:24:04', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '161bfae7-2abb-4c24-802b-15a7e2b5c5a3'	System	15 Nov 2020 03:24:38
User entered 'None (0)'	System	15 Nov 2020 03:24:38

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:24:20', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '161bfae7-2abb-4c24-802b-15a7e2b5c5a3'	System	15 Nov 2020 03:24:38
User entered 'Some interference with activity (2)'	System	15 Nov 2020 03:24:38

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:24:23', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '161bfae7-2abb-4c24-802b-15a7e2b5c5a3'	System	15 Nov 2020 03:24:38
User entered 'None (0)'	System	15 Nov 2020 03:24:38

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:24:26', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '161bfae7-2abb-4c24-802b-15a7e2b5c5a3'	System	15 Nov 2020 03:24:38
User entered 'None (0)'	System	15 Nov 2020 03:24:38

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:24:32', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '161bfae7-2abb-4c24-802b-15a7e2b5c5a3'	System	15 Nov 2020 03:24:38
User entered 'No (N)'	System	15 Nov 2020 03:24:38

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-14T22:24:34', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '161bfae7-2abb-4c24-802b-15a7e2b5c5a3'	System	15 Nov 2020 03:24:38
User entered '14 Nov 2020 22:24'	System	15 Nov 2020 03:24:38

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 5'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:16', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'ac2cd176-dfe1-4904-b435-075f8ae5ba43'	System	16 Nov 2020 01:03:54
User entered 'None (0)'	System	16 Nov 2020 01:03:54

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:18', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'ac2cd176-dfe1-4904-b435-075f8ae5ba43'	System	16 Nov 2020 01:03:54
User entered 'None (0)'	System	16 Nov 2020 01:03:54

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:23', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'ac2cd176-dfe1-4904-b435-075f8ae5ba43'	System	16 Nov 2020 01:03:54
User entered 'None (0)'	System	16 Nov 2020 01:03:54

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:31', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'ac2cd176-dfe1-4904-b435-075f8ae5ba43'	System	16 Nov 2020 01:03:54
User entered 'Some interference with activity (2)'	System	16 Nov 2020 01:03:54

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:36', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'ac2cd176-dfe1-4904-b435-075f8ae5ba43'	System	16 Nov 2020 01:03:54
User entered 'None (0)'	System	16 Nov 2020 01:03:54

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:39', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'ac2cd176-dfe1-4904-b435-075f8ae5ba43'	System	16 Nov 2020 01:03:54
User entered 'None (0)'	System	16 Nov 2020 01:03:54

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:45', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'ac2cd176-dfe1-4904-b435-075f8ae5ba43'	System	16 Nov 2020 01:03:54
User entered 'No (N)'	System	16 Nov 2020 01:03:54

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-15T20:03:47', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'ac2cd176-dfe1-4904-b435-075f8ae5ba43'	System	16 Nov 2020 01:03:54
User entered '15 Nov 2020 20:03'	System	16 Nov 2020 01:03:54

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 6'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:47:58', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '97f28c22-6dfd-45f7-85b4-63c4368c61ee'	System	17 Nov 2020 10:48:24
User entered 'None (0)'	System	17 Nov 2020 10:48:24

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:48:02', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '97f28c22-6dfd-45f7-85b4-63c4368c61ee'	System	17 Nov 2020 10:48:24
User entered 'None (0)'	System	17 Nov 2020 10:48:24

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:48:08', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '97f28c22-6dfd-45f7-85b4-63c4368c61ee'	System	17 Nov 2020 10:48:24
User entered 'None (0)'	System	17 Nov 2020 10:48:24

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:48:12', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '97f28c22-6dfd-45f7-85b4-63c4368c61ee'	System	17 Nov 2020 10:48:24
User entered 'None (0)'	System	17 Nov 2020 10:48:24

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:48:14', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '97f28c22-6dfd-45f7-85b4-63c4368c61ee'	System	17 Nov 2020 10:48:24
User entered 'None (0)'	System	17 Nov 2020 10:48:24

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:48:16', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '97f28c22-6dfd-45f7-85b4-63c4368c61ee'	System	17 Nov 2020 10:48:24
User entered 'None (0)'	System	17 Nov 2020 10:48:24

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:48:19', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '97f28c22-6dfd-45f7-85b4-63c4368c61ee'	System	17 Nov 2020 10:48:24
User entered 'No (N)'	System	17 Nov 2020 10:48:24

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T05:48:21', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: '97f28c22-6dfd-45f7-85b4-63c4368c61ee'	System	17 Nov 2020 10:48:24
User entered '17 Nov 2020 05:48'	System	17 Nov 2020 10:48:24

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
Data entry locked.	System	11 Nov 2020 14:56:23
User entered 'Day 7'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:47', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'db56f225-9fad-4f18-b1ab-d06e4f569f01'	System	18 Nov 2020 00:21:10
User entered 'None (0)'	System	18 Nov 2020 00:21:10

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:50', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'db56f225-9fad-4f18-b1ab-d06e4f569f01'	System	18 Nov 2020 00:21:10
User entered 'None (0)'	System	18 Nov 2020 00:21:10

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:53', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'db56f225-9fad-4f18-b1ab-d06e4f569f01'	System	18 Nov 2020 00:21:10
User entered 'None (0)'	System	18 Nov 2020 00:21:10

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:56', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'db56f225-9fad-4f18-b1ab-d06e4f569f01'	System	18 Nov 2020 00:21:10
User entered 'None (0)'	System	18 Nov 2020 00:21:10

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:20:59', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'db56f225-9fad-4f18-b1ab-d06e4f569f01'	System	18 Nov 2020 00:21:10
User entered 'None (0)'	System	18 Nov 2020 00:21:10

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:21:01', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'db56f225-9fad-4f18-b1ab-d06e4f569f01'	System	18 Nov 2020 00:21:10
User entered 'None (0)'	System	18 Nov 2020 00:21:10

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

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)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:21:05', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'db56f225-9fad-4f18-b1ab-d06e4f569f01'	System	18 Nov 2020 00:21:10
User entered 'No (N)'	System	18 Nov 2020 00:21:10

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (298fe7fb51074653)', Time: '2020-11-17T19:21:07', User OID: 'PatientReportedOutcome (US3712174)', ODM File OID: 'db56f225-9fad-4f18-b1ab-d06e4f569f01'	System	18 Nov 2020 00:21:10
User entered '17 Nov 2020 19:21'	System	18 Nov 2020 00:21:10

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 14:56:23

US3712174

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:28:09
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 14:56:23

US3712174

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:25:01

US3712174

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:25:01

US3712174

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:25:01

US3712174

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:25:01

US3712174

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:25:03

US3712174

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'I'	System	24 Nov 2020 13:25:03

US3712174

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:56:01

US3712174

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:56:01

US3712174

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:56:01

US3712174

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:56:01

US3712174

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:15:30

US3712174

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'I'	System	10 Dec 2020 21:15:30

US3712174

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:15:37

US3712174

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '02 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:15:37

US3712174

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:15:37

US3712174

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:15:37

US3712174

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:15:39

US3712174

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'I'	System	10 Dec 2020 21:15:39

US3712174

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:57:39

US3712174

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:57:39

US3712174

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:57:39

US3712174

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'VISIT3'	System	14 Dec 2020 13:57:39

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered empty.	System	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered empty.	System	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered empty.	System	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered empty.	System	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered empty.	System	14 Dec 2020 13:58:08

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53

US3712174

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53

US3712174

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:11

US3712174

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:11

US3712174

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:18

US3712174

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:18

US3712174

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 01:42:58
User entered '07:50'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 13:58:18

US3712174

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered '09 Dec 2020 07:50'	System	14 Dec 2020 13:58:18

US3712174

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:35:14
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 26-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 10:55:17
' (Site from DM). Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 26-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	03 Feb 2021 15:23:40
' answered with 'UPDATING' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 26-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	03 Feb 2021 11:43:16
' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 13:58:21

US3712174

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'I'	System	14 Dec 2020 13:58:21

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '10 Dec 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '14 Dec 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '17 Dec 2022 00:01'	System	20 Nov 2020 12:18:31

US3712174

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:18:31
Amendment Manager: User entered '21 Dec 2022 23:59'	System	20 Nov 2020 12:18:31

US3712174

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:35:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:26:13

US3712174

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:35:14
User entered '06 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:26:13

US3712174

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:35:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:26:13

US3712174

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:35:14
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:26:13

US3712174

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:35:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:26:17

US3712174

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:33:53
User entered 'I'	System	03 Feb 2021 15:26:17

US3712174

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:02:02

US3712174

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:02:02

US3712174

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:02:02

US3712174

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:02:02

US3712174

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:02:06

US3712174

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User entered 'I'	System	24 Feb 2021 18:02:06

US3712174

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:35:23

US3712174

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:35:23

US3712174

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:35:23

US3712174

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:35:23

US3712174

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:35:26

US3712174

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:34:05
User entered 'I'	System	17 Mar 2021 20:35:26

US3712174

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:30:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:59

US3712174

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:30:09
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:59

US3712174

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:30:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:59

US3712174

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:30:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:59

US3712174

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:30:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:51:00

US3712174

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 14:51:00

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:29:06

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '23 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 18:23:46

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:29:06

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '18:00'	(b) (4), (b) (6)	17 Nov 2020 18:23:46

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:29:06

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:38
User entered '23 Oct 2020 18:00'	System	17 Nov 2020 18:23:46

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:29:06

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	17 Nov 2020 18:23:46

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:29:06

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 18:23:46

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '19 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User closed query 'Per CDM : Please check from log line 1-5.It appears that O2 saturation and Temperature was not collected. If not collected, please consider recording it as Not Done. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 18:37:23
Query 'Per CDM : Please check from log line 1-5.It appears that O2 saturation and Temperature was not collected. If not collected, please consider recording it as Not Done.	(b) (4), (b) (6)	02 Feb 2021 16:26:59
' answered with 'UPDATED' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 16:26:53
User opened query 'Per CDM : Please check from log line 1-5.It appears that O2 saturation and Temperature was not collected. If not collected, please consider recording it as Not Done. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 16:03:28
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User entered '%'	System	02 Feb 2021 16:26:53
User entered empty.	System	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	02 Feb 2021 16:26:53
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:29:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:04

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '20 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	02 Feb 2021 16:27:09
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User entered '%'	System	02 Feb 2021 16:27:09
User entered empty.	System	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	02 Feb 2021 16:27:09
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:29:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:25:31

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '21 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	02 Feb 2021 16:27:18
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User entered '%'	System	02 Feb 2021 16:27:18
User entered empty.	System	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	02 Feb 2021 16:27:18
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:29:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:06

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '22 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	02 Feb 2021 16:30:00
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User entered '%'	System	02 Feb 2021 16:30:00
User entered empty.	System	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	02 Feb 2021 16:30:00
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:29:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:26:30

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '23 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	02 Feb 2021 16:30:10
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User entered '%'	System	02 Feb 2021 16:30:10
User entered empty.	System	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	02 Feb 2021 16:30:10
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:29:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 18:27:15

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:29:06

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered '23 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 18:28:05

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:29:06

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 18:07:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 18:28:05

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:29:06

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 18:07:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Nov 2020 17:38:33
Query 'Data is required. Please complete.' answered with 'test not done' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 18:31:50
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:28:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:28:05

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:29:06

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Nov 2020 17:38:34
Query 'Data is required. Please complete.' answered with 'test not done' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 18:31:53
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:28:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:28:05

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:29:06

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Nov 2020 17:38:40
Query 'Data is required. Please complete.' answered with 'test not done' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 18:31:56
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:28:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:28:05

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:29:06

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:28:05

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:29:06

[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 18:07:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:31:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 18:31:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 18:31:37
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:28:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:28:05

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:28:05

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:29:06

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:05
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:28:05

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:29:06

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:05

US3712174

Folder: Covid-19 Assessment 23 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:29:06

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:10
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 18:32:46

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:29:06

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:29:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:29:06

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:29:06

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:29:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:29:06

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:29:06

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:29:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:29:06

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:29:06

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:29:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:29:06

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:29:06

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:29:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:29:06

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:29:06

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:29:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:29:06

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:29:06

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:29:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:29:06

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:45:14
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:19

US3712174

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:39:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:11

US3712174

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:39:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:11

US3712174

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:39:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:11

US3712174

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:39:48
User entered 'SICKD1'	System	30 Mar 2021 14:35:11

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User entered empty.	System	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25
DataPoint set to visible.	System	30 Mar 2021 14:35:11

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25
DataPoint set to visible.	System	30 Mar 2021 14:35:11

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User entered empty.	System	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User entered empty.	System	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User entered empty.	System	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15
User entered empty.	System	30 Mar 2021 14:35:25

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15

US3712174

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:15

US3712174

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:21
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:31

US3712174

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:21
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:31

US3712174

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:29:06

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:32
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:12:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:47:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 14:35:42

US3712174

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:29:06

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:32
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:12:06
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 23 OCT 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 10:49:48
Query ' Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 23 OCT 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:47:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:47:23
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 23 OCT 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 05:21:26
User entered '23 Oct 2020'	(b) (4), (b) (6)	30 Mar 2021 14:35:42

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:03

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:03

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:03

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	30 Mar 2021 14:36:03

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 14:36:05

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:07

US3712174

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:07

US3712174

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:29:06

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:10

US3712174

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:29:06

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:36:10

US3712174

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

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:28:28

US3712174

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

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:28:28

US3712174

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

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[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 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:28:28

US3712174

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

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 15:28:28

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '26 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:17:28
User entered '06 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 15:40:05

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

[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 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:45:53

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:05

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
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 09:45:53

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:05

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:05

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:05

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:05

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:05

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered '1'	System	03 Feb 2021 15:40:05

US3712174

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

Form: Unblinding

Generated On: 10 Jun 2021 09:29:06

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'I'	System	03 Feb 2021 15:40:05

US3712174

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered empty.	System	03 Feb 2021 15:40:49
DataPoint set to visible.	System	03 Feb 2021 15:40:05

US3712174

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered empty.	System	03 Feb 2021 15:40:49
DataPoint set to visible.	System	03 Feb 2021 15:40:05

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '13:37'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered '26 Jan 2021 13:37'	System	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '54'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'bpm'	System	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '16'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'breaths/min'	System	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '143'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'mmHg'	System	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '81'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'mmHg'	System	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered empty.	System	03 Feb 2021 15:40:49
DataPoint set to visible.	System	03 Feb 2021 15:40:05

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '14:55'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered '26 Jan 2021 14:55'	System	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '37.0' C	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '96'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'bpm'	System	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '16'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'breaths/min'	System	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '145'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'mmHg'	System	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '86'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:49

US3712174

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'mmHg'	System	03 Feb 2021 15:40:49

US3712174

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:53

US3712174

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:40:53

US3712174

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

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:41:03

US3712174

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

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:41:03

US3712174

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

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

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 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:41:03

US3712174

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

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'mRNA-1273'	System	03 Feb 2021 15:41:03
DataPoint set to visible.	System	03 Feb 2021 15:40:05

US3712174

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

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:41:03

US3712174

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

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '14:22'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:41:03

US3712174

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

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered '26 Jan 2021 14:22'	System	03 Feb 2021 15:41:03

US3712174

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

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:41:03

US3712174

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

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'ONCE'	System	03 Feb 2021 15:41:03

US3712174

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

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 15:41:03

US3712174

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:33:16

US3712174

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:33:16

US3712174

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '12:57'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:33:16

US3712174

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered '26 Jan 2021 12:57'	System	03 Feb 2021 15:33:16

US3712174

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:33:22

US3712174

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:33:22

US3712174

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '12:58'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:33:22

US3712174

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:06

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered '26 Jan 2021 12:58'	System	03 Feb 2021 15:33:22

US3712174

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

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:41:43

US3712174

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'I'	System	03 Feb 2021 15:41:43

US3712174

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:42:23

US3712174

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	02 Mar 2021 13:02:38
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	System	02 Mar 2021 13:02:38
User entered '02 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 13:02:38
Amendment Manager: User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Feb 2021 00:59:07
Amendment Manager: User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:59:07
User entered '02 Dec 2020'	(b) (4), (b) (6)	03 Feb 2021 15:42:23

US3712174

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:42:23

US3712174

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:42:23

US3712174

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:42:27

US3712174

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'I'	System	03 Feb 2021 15:42:27

US3712174

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered '1'	System	03 Feb 2021 15:42:27
DataPoint set to visible.	System	03 Feb 2021 15:42:27

US3712174

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:05:14

US3712174

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:05:14

US3712174

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[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 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:05:14

US3712174

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'OLD29'	System	02 Mar 2021 13:05:14

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '08:40'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered '01 Mar 2021 08:40'	System	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '73'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'bpm'	System	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'breaths/min'	System	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '130'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'mmHg'	System	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '77'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'mmHg'	System	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '10:16'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered '01 Mar 2021 10:16'	System	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '58'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'bpm'	System	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'breaths/min'	System	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '137'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'mmHg'	System	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '81'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'mmHg'	System	02 Mar 2021 13:08:44

US3712174

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:56

US3712174

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:08:56

US3712174

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:09:20

US3712174

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:09:20

US3712174

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

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 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:09:20

US3712174

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'mRNA-1273'	System	02 Mar 2021 13:09:20
DataPoint set to visible.	System	03 Feb 2021 15:42:27

US3712174

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:09:20

US3712174

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '09:46'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:09:20

US3712174

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered '01 Mar 2021 09:46'	System	02 Mar 2021 13:09:20

US3712174

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:09:20

US3712174

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'ONCE'	System	02 Mar 2021 13:09:20

US3712174

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:06

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 13:09:20

US3712174

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:09:23

US3712174

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'I'	System	02 Mar 2021 13:09:23

US3712174

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:18:53

US3712174

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '08 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:18:53

US3712174

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:18:53

US3712174

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:18:53

US3712174

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:18:57

US3712174

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:30
User entered 'I'	System	17 Mar 2021 20:18:57

US3712174

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:08

US3712174

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:08

US3712174

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:08

US3712174

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 14:33:08

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 14:33:12

US3712174

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:51

US3712174

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:51

US3712174

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:57

US3712174

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:57

US3712174

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '13:22'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:33:57

US3712174

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 13:22'	System	30 Mar 2021 14:33:57

US3712174

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:29:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:21
User signature succeeded.	William Smith (b) (4)	12 Mar 2021 22:25:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:59:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 13:10:18
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 18:32:19

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:38:44
User entered 'USA-US068-2021-mRNA-1273-P301000016'	System	02 Mar 2021 14:36:32
User entered 'New'	(b) (4), (b) (6)	02 Mar 2021 14:36:32

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this worsening AE and please note, there is no baseline condition (MH or prior AE record) that would support this worsening event. Please review and update to record the baseline condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:07:48
Query 'Per DM CLR: Please review this worsening AE and please note, there is no baseline condition (MH or prior AE record) that would support this worsening event. Please review and update to record the baseline condition as appropriate. Otherwise, clarify.' answered with 'added to medical history ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 19:44:41
User opened query 'Per DM CLR: Please review this worsening AE and please note, there is no baseline condition (MH or prior AE record) that would support this worsening event. Please review and update to record the baseline condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:48:20
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) (b) (4)	06 Mar 2021 12:46:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 12:46:00
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
Data point term sent to Coder	System	02 Mar 2021 13:18:27
User entered 'worsening of degenerative disc disease'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '11 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '13 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '1'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '11 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '13 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 13:47:17
User closed query 'Please confirm, as the initial SAE report (paper form in source) does not indicate important medical event. If confirmed update or clarify and update paper.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 13:47:15
Query 'Please confirm, as the initial SAE report (paper form in source) does not indicate important medical event. If confirmed update or clarify and update paper.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:45:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 19:45:13
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:45:13
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User opened query 'Please confirm, as the initial SAE report (paper form in source) does not indicate important medical event. If confirmed update or clarify and update paper.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 21:55:14
User entered '1'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'None (NONE)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm no Concomitant Medication was given for this AE. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 11:55:38
Query 'Per CDM: Please confirm no Concomitant Medication was given for this AE. ' answered with 'per subject, no medications ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 19:51:53
User opened query 'Per CDM: Please confirm no Concomitant Medication was given for this AE. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 19:30:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 11:56:10
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 19:53:04
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:48:31
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 13:47:46
User closed query 'Please review spelling and dates/years and update as needed.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 13:47:41
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:03:48
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:03:41
User closed query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 12:44:40
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 12:44:39
User closed query 'PV Query: Please confirm if degenerative disc disease is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If degenerative disc disease is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 12:44:35
Query 'PV Query: Please confirm if degenerative disc disease is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If degenerative disc disease is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' answered with 'added to medical history ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 19:57:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'waiting for medical records ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 19:56:53
Query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'waiting for medical records ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 19:56:43
Query 'Please review spelling and dates/years and update as needed.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:56:33
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 19:56:28
User entered 'ON 01 MARCH 2021 SUBJECT WAS IN CLINIC FOR OLV-2 AND REPORTED THAT THEY WERE HOSPITALIZED ON 11 FEBRUARY 2021 DUE TO WORSENING OF DEGENERATIVE DISC DISEASE THAT BEGAN IN 2010. ON 11 FEBRUARY 2021 SUBJECT WAS ADMITTED TO FORT SANDERS REGIONAL MEDICAL CENTER FOR ANTERIOR Discectomy CERVICAL FUSION OF C4, C5, C6, C7 WAS ILIAC CREST DONE GRAFTING AND ANTERIOR PLATING OF C4 AND C7. SUBJECT STAYED IN HOSPITAL FOR 2 DAYS AND WAS DISCHARGED HOME. PENDING MEDICAL RECORDS FOR ADDITIONAL INFORMATION.'	(b) (4), (b) (6)	17 Mar 2021 19:56:28
reason for change: Data Entry Error		
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:04:26

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if degenerative disc disease is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If degenerative disc disease is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:04:13
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:03:10
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:00:49
User opened query 'Please review spelling and dates/years and update as needed.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:43
User entered 'On 01 March 2021 subject was in clinic on 11 February 20221 due to worsening of Degenerative disc disease that began in 2010. On 11 February 2021 subject was admitted to Fort Sanders Regional Medical Center for anterior discectomy cervical fusion of C4, C5, C6, C7 was iliac crest done grafting and anterior plating of C4 and C7. Subject stayed in hospital for 2 days and was discharged home. Pending medical records for additional information.'	(b) (4), (b) (6)	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 13:17:33

US3712174

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 13:17:33

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:29:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:21
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:06:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 17:09:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 17:09:30
Data point term sent to Coder	System	15 Oct 2020 17:08:38
User entered 'losartan'	(b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '50'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 17:07:47

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 17:09:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 17:09:32
Data point term sent to Coder	System	15 Oct 2020 17:08:39
User entered 'metoprolol'	(b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '12.5'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 17:08:20

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 17:10:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 17:10:28
Data point term sent to Coder	System	15 Oct 2020 17:09:40
User entered 'pantoprazole'	(b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Gastroesophageal reflux disease'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '40'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 17:09:09

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 17:10:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 17:10:29
Data point term sent to Coder	System	15 Oct 2020 17:09:46
User entered 'zyrtec'	(b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'seasonal allergies'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '10'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 17:09:37

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: INDOMETACIN, PRODUCTSYNONYM: INDOMETHACIN [INDOMETACIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Feb 2021 15:32:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:32:25
Data point term sent to Coder	System	03 Feb 2021 15:31:20
User entered 'indomethacin'	(b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'GOUT'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '50'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 15:30:38

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Feb 2021 15:33:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:33:27
Data point term sent to Coder	System	03 Feb 2021 15:32:20
User entered 'allopurinol'	(b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'GOUt'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '300'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 15:31:32

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
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)	03 Feb 2021 15:33:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 15:33:26
Data point term sent to Coder	System	03 Feb 2021 15:32:29
User entered 'influenza vaccine'	(b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User closed query 'Per DM CLR: Please review response as vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 16:19:54
Query 'Per DM CLR: Please review response as vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	17 Mar 2021 19:46:38
' answered with 'updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:46:34
User opened query 'Per DM CLR: Please review response as vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 02:26:49
User entered 'No (N)'	(b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'flu prevention'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '0.5'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User entered empty.	System	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User entered empty.	System	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:31
User entered empty.	System	03 Feb 2021 15:32:29

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Mar 2021 07:56:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 07:56:29
Data point term sent to Coder	System	30 Mar 2021 14:41:50
User entered 'hydrocodone '	(b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'quadruple cervical fusion with bone graft'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '5'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'every 6 hours'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User entered empty.	System	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User entered empty.	System	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:36
User entered empty.	System	30 Mar 2021 14:41:10

US3712174

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:29:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:21
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:42:21
User closed query 'Please ensure to enter the Anterior Discectomy Cervical Fusion of C4, C5, C6, C7' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:07:11
Query 'Please ensure to enter the Anterior Discectomy Cervical Fusion of C4, C5, C6, C7' answered with 'updating' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:52:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:52:07
User opened query 'Please ensure to enter the Anterior Discectomy Cervical Fusion of C4, C5, C6, C7' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:04:03
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 18:32:24

US3712174

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:06

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:52:51

US3712174

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered 'Anterior Discectomy Cervical Fusion of C4, C5, C6, C7'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:52:51

US3712174

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 19:52:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 19:52:57
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:52:57
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 19:52:51
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:52:51

US3712174

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:06

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:17
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:52:51

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'USA-US068-2021-MRNA-1273-P301000016'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Yes (Y)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Yes (Y)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Other medically important event](#)

Audit	User	Time (GMT)
User closed query 'Please confirm response.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:06:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:44:50
Query 'Please confirm response.' answered with 'no is correct ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 20:00:55
Un-reviewed for Safety.	System	17 Mar 2021 19:45:13
User entered 'No (N)'	System	17 Mar 2021 19:45:13
User opened query 'Please confirm response.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 21:57:22
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Yes (Y)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'William'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Smith'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered empty.	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered '801 North Weisgarber Rd'	(b) (4), (b) (6)	17 Mar 2021 20:02:17

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered empty.	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered 'Knoxville'	(b) (4), (b) (6)	17 Mar 2021 20:02:17

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered empty.	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered 'TN'	(b) (4), (b) (6)	17 Mar 2021 20:02:17

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered (b) (4)	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 20:02:17
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:02:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered (b) (4) '	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered 'US'	System	02 Mar 2021 14:39:08

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Mar 2021 12:45:00
User entered '1'	System	02 Mar 2021 14:39:08

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'USA-US068-2021-MRNA-1273-P301000016'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Yes (Y)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Yes (Y)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Other medically important event](#)

Audit	User	Time (GMT)
User closed query 'Please confirm response.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:06:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:44:50
Query 'Please confirm response.' answered with 'no is correct ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 20:00:55
Un-reviewed for Safety.	System	17 Mar 2021 19:45:13
User entered 'No (N)'	System	17 Mar 2021 19:45:13
User opened query 'Please confirm response.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 21:57:22
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Yes (Y)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'William'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Smith'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered empty.	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered '801 North Weisgarber Rd'	(b) (4), (b) (6)	17 Mar 2021 20:02:17

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered empty.	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered 'Knoxville'	(b) (4), (b) (6)	17 Mar 2021 20:02:17

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered empty.	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered 'TN'	(b) (4), (b) (6)	17 Mar 2021 20:02:17

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered (b) (4)	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 20:02:17
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:02:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered (b) (4)	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered 'US'	System	02 Mar 2021 14:39:08

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Mar 2021 12:45:00
User entered '1'	System	02 Mar 2021 14:39:08

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:29:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '02/Mar/2021 09:39'	(b) (4) System	02 Mar 2021 14:39:08

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:29:06

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.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 14:39:08

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'USA-US068-2021-MRNA-1273-P301000016'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Yes (Y)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Yes (Y)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'No (N)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Other medically important event](#)

Audit	User	Time (GMT)
User closed query 'Please confirm response.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:06:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:44:50
Query 'Please confirm response.' answered with 'no is correct ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 20:00:55
Un-reviewed for Safety.	System	17 Mar 2021 19:45:13
User entered 'No (N)'	System	17 Mar 2021 19:45:13
User opened query 'Please confirm response.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 21:57:22
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Yes (Y)'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'William'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered 'Smith'	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered empty.	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered '801 North Weisgarber Rd'	(b) (4), (b) (6)	17 Mar 2021 20:02:17

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered empty.	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered 'Knoxville'	(b) (4), (b) (6)	17 Mar 2021 20:02:17

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered empty.	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered 'TN'	(b) (4), (b) (6)	17 Mar 2021 20:02:17

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:45:27
Un-reviewed for Safety.	System	18 Mar 2021 12:45:00
User entered (b) (4)	System	18 Mar 2021 12:45:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:44:50
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 20:02:17
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 20:02:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:38:57
User entered (b) (4)	System	02 Mar 2021 14:36:32

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:44:50
User entered 'US'	System	02 Mar 2021 14:39:08

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Mar 2021 12:45:00
User entered '1'	System	02 Mar 2021 14:39:08

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:29:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:37:48
User entered '18/Mar/2021 12:44'	(b) (4) System	18 Mar 2021 12:45:00

US3712174

Folder: SAE USA-US068-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:29:06

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.	William Smith (b) (4)	05 Apr 2021 00:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:45:27
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 12:45:00