

US3172374 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:30:31

All time stamps listed in this document are displayed in GMT

US3172374

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:37:27

Generated On: 09 Jun 2021 15:30:31

Participant ID

US3172374

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

US3172374

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

Visit date (dd MMM yyyy)	16 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3172374

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 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 checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 13:37:36

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	LEFT EYE CATARACTS (PLANNING SURGERY NEXT YEAR)
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	DIABETES TYPE 1
Start date (dd MMM yyyy)	UN UNK 1966
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 1966
Start Year (derived)	1966
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	DIABETIC POLYNEUROPATHY (SENSORIAL BILATERAL LOWER EXTREMETIES)
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	CHRONIC HIP PAIN
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172374

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	CATARACT RIGHT EYE SURGERY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Condition	LEFT FOOT 3RD TOE AMPUTATION DUE TO PHYSICAL TRAUMA SURGERY
Start date (dd MMM yyyy)	UN APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	08:38 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 08:38
Height (xxx.x)	171.6 cm
Weight (xxx.x)	71.0 kg
BMI (xxx.x)	24.11148 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172374

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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 NOT WORKING

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) 17 Feb 2021 13:37:36

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

What was the date of randomization? (dd MMM yyyy) 16 OCT 2020

What was the participant's randomization number? 145124

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) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 08:28
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 11:48
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:18 (24 HR)

Treatment Date and Time (derived) 16 OCT 2020 11:18

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) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

Collection date (dd MMM yyyy)	16 OCT 2020
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Collection time (00:00-23:59)	10:55 (24 HR)
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Collection date and time (derived)	16 OCT 2020 10:55
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US3172374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Collection date (dd MMM yyyy)			16 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:58	16 OCT 2020 10:58
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

97.7 °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

16 OCT 2020 11:55

PC Open Date & Time

16 OCT 2020 11:38

PC Close Date & Time

16 OCT 2020 14:08

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 16 OCT 2020 15:03

PC Close Date & Time 17 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

93.9 °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

17 OCT 2020 19:42

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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 18:40

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

96.8 °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

19 OCT 2020 17:17

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 22:53

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

97.8 °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

21 OCT 2020 20:08

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

22 OCT 2020 18:00

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

16 OCT 2020 11:55

PC Open Date & Time

16 OCT 2020 11:38

PC Close Date & Time

16 OCT 2020 14:08

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 17:25

PC Open Date & Time

16 OCT 2020 15:03

PC Close Date & Time

17 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 19:42

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 18:41

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 17:18

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

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 22:54

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 20:09

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 18:00

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 11:56
PC Open Date & Time	16 OCT 2020 11:38
PC Close Date & Time	16 OCT 2020 14:08

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 17:24
PC Open Date & Time	16 OCT 2020 15:03
PC Close Date & Time	17 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 19:43
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

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EAB) (1725)

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 17:18
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

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EAB) (1725)

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 22:54
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

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)

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 20:10
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 18:01
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3172374

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

Visit date (dd MMM yyyy)	13 NOV 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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)	13 NOV 2020
Time of assessment (00:00-23:59)	09:51 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 09:51
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 12:43
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3172374

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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) 13 NOV 2020

What was the treatment time? (00:00-23:59) 12:13 (24 HR)

Treatment Date and Time (derived) 13 NOV 2020 12:13

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

What was the frequency of the study treatment dosing? ONCE

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

US3172374

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

Collection date (dd MMM yyyy)	13 NOV 2020
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Collection time (00:00-23:59)	11:30 (24 HR)
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Collection date and time (derived)	13 NOV 2020 11:30
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US3172374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Collection date (dd MMM yyyy)			13 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:32	13 NOV 2020 11:32
Nasopharyngeal Swab 2	No		

US3172374

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

98.8 °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

13 NOV 2020 12:43

PC Open Date & Time

13 NOV 2020 12:33

PC Close Date & Time

13 NOV 2020 15:03

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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 96.4 °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	13 NOV 2020 17:47
PC Open Date & Time	13 NOV 2020 15:58
PC Close Date & Time	14 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 NOV 2020 18:42

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

94.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 NOV 2020 19:03

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

93.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 NOV 2020 19:40

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

97.6 °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 NOV 2020 17:24

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 NOV 2020 22:42

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

13 NOV 2020 12:44

PC Open Date & Time

13 NOV 2020 12:33

PC Close Date & Time

13 NOV 2020 15:03

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

13 NOV 2020 17:47

PC Open Date & Time

13 NOV 2020 15:58

PC Close Date & Time

14 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

14 NOV 2020 18:42

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

16 NOV 2020 19:04

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

17 NOV 2020 19:40

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

18 NOV 2020 17:24

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

19 NOV 2020 22:42

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

No ☒

Yes ☐

PC Time stamp	13 NOV 2020 12:44
PC Open Date & Time	13 NOV 2020 12:33
PC Close Date & Time	13 NOV 2020 15:03

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

No ☒

Yes ☐

PC Time stamp	13 NOV 2020 17:48
PC Open Date & Time	13 NOV 2020 15:58
PC Close Date & Time	14 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

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 ☒

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

Yes <input type="checkbox"/>	
PC Time stamp	14 NOV 2020 18:43
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

Yes ☐

PC Time stamp

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

Yes <input type="checkbox"/>	
PC Time stamp	16 NOV 2020 19:04
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

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)

113 of 2464

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 19:40
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

115 of 2464

EAB) (1725)

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

Yes <input type="checkbox"/>	
PC Time stamp	18 NOV 2020 17:25
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

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 ☒

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

Yes <input type="checkbox"/>	
PC Time stamp	19 NOV 2020 22:42
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3172374

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

Visit date (dd MMM yyyy)	11 DEC 2020
--------------------------	-------------

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

Folder OID	VISIT3
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US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 DEC 2020
Time of assessment (00:00-23:59)	07:25 (24 HR)
Vital Signs Date and Time (derived)	11 DEC 2020 07:25
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172374

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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.

US3172374

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

Collection date (dd MMM yyyy)	11 DEC 2020
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Collection time (00:00-23:59)	08:48 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	11 DEC 2020 08:48
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US3172374

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 08:49:55
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 12:02:24

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 10:45:29

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 19:18:02

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 00:01:41
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 08:46:56

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 11:58:08

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 14:12:44

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 10:31:59

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 19:11:20

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 00:01:53

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 00:01:57

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 12:28:54

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 00:12:49

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 00:05:04

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 208

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

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 215

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

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 222

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

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 250

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

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐ 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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐ 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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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="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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	11 NOV 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	06 JAN 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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03 FEB 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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17 FEB 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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

Date and time of submission

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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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03 MAR 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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10 MAR 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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17 MAR 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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24 MAR 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐ 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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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07 APR 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐ 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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

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14 APR 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐
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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	08 SEP 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐ 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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	15 DEC 2022 23:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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 ☐ 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 ☐

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2022 00:01
Patient Cloud Close Date & Time	22 DEC 2022 23:59

US3172374

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:30:31

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 11:58:24

US3172374

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

MISSED OPEN LABEL

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:33:58

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

MISSED, SUBJECT IN OPEN
LABEL.

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:33:58

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:33:58

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:33:58

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

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

Visit date (dd MMM yyyy)	28 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 APR 2021
Time of assessment (00:00-23:59)	07:14 (24 HR)
Vital Signs Date and Time (derived)	28 APR 2021 07:14
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172374

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 APR 2021

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

US3172374

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

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

Collection date (dd MMM yyyy)	28 APR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	07:44 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	28 APR 2021 07:44
------------------------------------	-------------------

US3172374

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172374

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 17 Feb 2021 13:37:27

Generated On: 09 Jun 2021 15:30:31

Date of Contact	05 FEB 2021
Time of Contact	13:07
Date and Time of Contact (derived)	05 FEB 2021 13:07
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

	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	04 FEB 2021
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

	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	05 FEB 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	37.0 C
-------------	--------

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

Cough	None	<input 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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US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

	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	06 FEB 2021
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

	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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

	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	07 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

	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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

	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	08 FEB 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

	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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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"/>

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

Symptom Day

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

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

	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	09 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 17 Feb 2021 13:37:27

Generated On: 09 Jun 2021 15:30:31

Date of Visit	05 FEB 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	05 FEB 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 17 Feb 2021 13:37:27

Generated On: 09 Jun 2021 15:30:31

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 09 Mar 2021 14:43:50

Generated On: 09 Jun 2021 15:30:31

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	

US3172374

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

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

Visit date (dd MMM yyyy)	05 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 FEB 2021
Time of assessment (00:00-23:59)	13:07 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 13:07
Height (xxx.x)	171.6 cm
Weight (xxx.x)	069.9 kg
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172374

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 FEB 2021

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

US3172374

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

05 FEB 2021

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 14:43:50

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 14:43:50

Generated On: 09 Jun 2021 15:30:31

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) _____

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 14:43:50

Generated On: 09 Jun 2021 15:30:31

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.

US3172374

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 09 Mar 2021 14:43:50

Generated On: 09 Jun 2021 15:30:31

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3172374

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 26 JAN 2021

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

Folder OID UNBLND_DECIDE

US3172374

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:33:58

Generated On: 09 Jun 2021 15:30:31

Date of updated informed consent (dd MMM yyyy)	06 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 (dd MMM yyyy)	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

US3172374

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

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

US3172374

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

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)	11:59 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 11:59
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3172374

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

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)	15:24 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 15:24
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3172374

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

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3172374

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

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

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) 14:54 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 14:54

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

US3172374

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

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

Collection date (dd MMM yyyy)	26 JAN 2021
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Collection time (00:00-23:59)	12:57 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 JAN 2021 12:57
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US3172374

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00 - 23:59)

12:59

Collection Date and Time (derived)

26 JAN 2021 12:59

US3172374

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

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:35

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:37:36

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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 FEB 2021
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 09:30
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)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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 FEB 2021
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:48
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)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3172374

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3172374

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

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 FEB 2021

What was the treatment time? (00:00-23:59) 11:18 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 11:18

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

US3172374

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 14:01:21

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 14:43:50

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 14:43:50

Generated On: 09 Jun 2021 15:30:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172374

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:33:58

Generated On: 09 Jun 2021 15:30:31

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

Visit date (dd MMM yyyy)	26 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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US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:33:58

Generated On: 09 Jun 2021 15:30:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 MAR 2021
Time of assessment (00:00-23:59)	07:41 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 07:41
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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172374

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:33:58

Generated On: 09 Jun 2021 15:30:31

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.

US3172374

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:33:58

Generated On: 09 Jun 2021 15:30:31

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

Collection date (dd MMM yyyy)	26 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	08:06 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 MAR 2021 08:06
------------------------------------	-------------------

US3172374

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:37:27

Generated On: 09 Jun 2021 15:30:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

AEID

Adverse event

UPPER RESPIRATORY
INFECTION - URI

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

31 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

AEID	USA-US118-2021-MRNA-1273-P30 1000018
Adverse event	LEFT FEET SECOND TOE PRESSURE ULCER STAGE III
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)	19 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 APR 2021
Hospital Discharge Date (dd MMM yyyy)	22 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

DURING THE VISIT DAY 209
SUBJECT REPORTED AN
HOSPITALIZATION PERIOD
FROM 19APR2021 UNTIL
22APR2021 AT UNIVERSITY OF
MIAMI HOSPITAL DUE TO LEFT
FEET SECOND TOE PRESSURE
ULCER. THE EVENT IS STILL
ONGOING. PCP AND FEET CARE
MD ARE TAKING CARE OF
SUBJECT FOR FOLLOW UP. WE
WILL REQUEST RECORDS
FROM THE HOSPITAL.

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

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:37:27

Generated On: 09 Jun 2021 15:30:31

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication SYMBICORT 1 PUFF

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 160/4.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

	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 1999
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) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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

AT NIGHT

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

	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 1999	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID RELUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 1

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication DIABETIC POLYNEUROPATHY

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) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

	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 1999	
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"/>

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC HIP PAIN

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication RIXULTI

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.50

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication SEROQUEL

Prophylaxis Yes ☐
No ☒

Indication BIP[OLAR/ DEPRESSION/
INSOMNIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication NYQUIL - (ACETAMINOPHEN
650MG, DEXTROMETHORPHAN
30MG, DOXYLAMINE 12.5 MG)

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION - URI

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 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)	04 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

Name of Medication	MUPIROCIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LEFT FOOT 2ND TOE PRESSURE ULCER STAGE III
Dose per administration	2
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	%
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172374

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 13:37:27

Generated On: 09 Jun 2021 15:30:31

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3172374

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:30:31

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

US3172374

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:30:31

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 ☐

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

SAEID	USA-US118-2021-MRNA-1273-P301000018
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

SAEID	USA-US118-2021-MRNA-1273-P301000018
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	28/APR/2021 11:45
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

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:26:18

Generated On: 09 Jun 2021 15:30:31

SAEID	USA-US118-2021-MRNA-1273-P301000018
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	28/APR/2021 12:56
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

US3172374 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172374

Form: Participant Creation

Generated On: 09 Jun 2021 15:30:31

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'US3172374'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 12:38:31

US3172374

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:27:13

US3172374

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 12:38:32

US3172374

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:27:13

US3172374

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'SCRN'	System	16 Oct 2020 15:27:13

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 12:38:33

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '61'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'YEARS'	System	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '61'	System	16 Oct 2020 15:28:24

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Male (M)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	16 Oct 2020 15:30:32
	(b) (4)	

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:30:32

US3172374

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:28:24

US3172374

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Oct 2020'	System	16 Oct 2020 15:28:24

US3172374

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2020'	System	16 Oct 2020 15:28:24

US3172374

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'Amendment 3 (3)'	Mariete Rendon (b) (4)	16 Oct 2020 15:28:24
	(b) (4)	

US3172374

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:28:24

US3172374

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:28:24

US3172374

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:28:24

US3172374

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:28:24

US3172374

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 12:38:32

US3172374

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'I'	System	16 Oct 2020 15:28:33

US3172374

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:28:33

US3172374

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:30:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:39:09

US3172374

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Left cataract - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 23:57:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 23:57:44
Data point term sent to Coder	System	16 Oct 2020 15:40:02
User entered 'LEFT EYE CATARACTS (PLANNING SURGERY NEXT YEAR)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:39:49

US3172374

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:39:49

US3172374

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:39:49

US3172374

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:39:49

US3172374

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:39:49

US3172374

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:39:49

US3172374

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 2017'	System	16 Oct 2020 15:39:49

US3172374

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2017'	System	16 Oct 2020 15:39:49

US3172374

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:39:49

US3172374

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:39:49

US3172374

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:41:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:41:28
Data point term sent to Coder	System	16 Oct 2020 15:41:05
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:20

US3172374

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1999'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:20

US3172374

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:20

US3172374

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	16 Oct 2020 15:40:20
	(b) (4)	

US3172374

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:20

US3172374

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:20

US3172374

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1999'	System	16 Oct 2020 15:40:20

US3172374

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1999'	System	16 Oct 2020 15:40:20

US3172374

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:40:20

US3172374

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:40:20

US3172374

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
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) (b) (4)	16 Oct 2020 15:41:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:41:28
Data point term sent to Coder	System	16 Oct 2020 15:41:05
User entered 'HYPERTENSION'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:40

US3172374

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1999'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:40

US3172374

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:40

US3172374

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:40

US3172374

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:40

US3172374

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:40:40

US3172374

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1999'	System	16 Oct 2020 15:40:40

US3172374

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1999'	System	16 Oct 2020 15:40:40

US3172374

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:40:40

US3172374

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:40:40

US3172374

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:41:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:41:28
Data point term sent to Coder	System	16 Oct 2020 15:41:06
User entered 'HYPERLIPIDEMIA'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:41:03

US3172374

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1999'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:41:03

US3172374

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:41:03

US3172374

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:41:03

US3172374

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:41:03

US3172374

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:41:03

US3172374

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1999'	System	16 Oct 2020 15:41:03

US3172374

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1999'	System	16 Oct 2020 15:41:03

US3172374

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:41:03

US3172374

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:41:03

US3172374

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:43:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:43:30
Data point term sent to Coder	System	16 Oct 2020 15:42:07
User entered 'ACID REFLUX'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:41:20

US3172374

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1990'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:41:20

US3172374

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	16 Oct 2020 15:41:20
	(b) (4)	

US3172374

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:41:20

US3172374

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:41:20

US3172374

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	16 Oct 2020 15:41:20
	(b) (4)	

US3172374

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1990'	System	16 Oct 2020 15:41:20

US3172374

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1990'	System	16 Oct 2020 15:41:20

US3172374

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:41:20

US3172374

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:41:20

US3172374

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:43:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:43:31
Data point term sent to Coder	System	16 Oct 2020 15:42:07
User entered 'CONSTIPATION'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:02

US3172374

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1990'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:02

US3172374

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:02

US3172374

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:02

US3172374

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:02

US3172374

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:02

US3172374

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1990'	System	16 Oct 2020 15:42:02

US3172374

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1990'	System	16 Oct 2020 15:42:02

US3172374

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:42:02

US3172374

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:42:02

US3172374

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Impaired gastric emptying, LLT: Gastroparesis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:44:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:44:35
Data point term sent to Coder	System	16 Oct 2020 15:43:08
User entered 'GASTROPARESIS'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:42

US3172374

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 2010'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:42

US3172374

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:42

US3172374

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:42

US3172374

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:42

US3172374

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:42:42

US3172374

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 2010'	System	16 Oct 2020 15:42:42

US3172374

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2010'	System	16 Oct 2020 15:42:42

US3172374

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:42:42

US3172374

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:42:42

US3172374

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type 1 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:45:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:45:24
Data point term sent to Coder	System	16 Oct 2020 15:44:11
User entered 'DIABETES TYPE 1'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:43:23

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1966'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:43:23

US3172374

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:43:23

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:43:23

US3172374

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:43:23

US3172374

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:43:23

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1966'	System	16 Oct 2020 15:43:23

US3172374

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1966'	System	16 Oct 2020 15:43:23

US3172374

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:43:23

US3172374

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:43:23

US3172374

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User closed query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 21). ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:17:15
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of DIABETIC POLYNEUROPATHY (SENSORIAL IRRADICATED TO HANDS). 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)	27 Oct 2020 11:15:48
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic polyneuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 22:33:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 22:33:18
Query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 21). ' answered with 'data split as per query request' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 20:17:15
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of DIABETIC POLYNEUROPATHY (SENSORIAL IRRADICATED TO HANDS). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'condition already states Bilateral' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 20:16:48
Data point term sent to Coder	System	22 Oct 2020 20:15:40
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 20:15:27

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Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
User entered 'DIABETIC POLYNEUROPATHY (SENSORIAL BILATERAL LOWER EXTREMETIES)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Oct 2020 20:15:27
User opened query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 21). ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:10:10
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of DIABETIC POLYNEUROPATHY (SENSORIAL IRRADICATED TO HANDS). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:09:55
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic polyneuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 11:52:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 11:52:28
Data point term sent to Coder	System	16 Oct 2020 15:48:18
User entered 'DIABETIC POLYNEUROPATHY (SENSORIAL IRRADICATED TO HANDS, BILATERAL LOWER EXTREMETIES)'	Mariete Rendon (b) (4)	16 Oct 2020 15:48:17

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Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1999'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:48:17

US3172374

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:48:17

US3172374

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:48:17

US3172374

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:48:17

US3172374

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:48:17

US3172374

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1999'	System	16 Oct 2020 15:48:17

US3172374

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1999'	System	16 Oct 2020 15:48:17

US3172374

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:48:17

US3172374

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:48:17

US3172374

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:54:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:54:38
Data point term sent to Coder	System	16 Oct 2020 15:53:25
User entered 'OSTEOPOROSIS'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:33

US3172374

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1999'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:33

US3172374

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:33

US3172374

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:33

US3172374

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	16 Oct 2020 15:52:33
	(b) (4)	

US3172374

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:33

US3172374

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1999'	System	16 Oct 2020 15:52:33

US3172374

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1999'	System	16 Oct 2020 15:52:33

US3172374

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:52:33

US3172374

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:52:33

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of CHRONIC JOINT PAIN. 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 15:06:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:45:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:45:40
Data point term sent to Coder	System	23 Oct 2020 19:44:35
Query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of CHRONIC JOINT PAIN. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 19:44:13
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 19:44:06
User entered 'CHRONIC Hip PAIN' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 19:44:06
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of CHRONIC JOINT PAIN. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:10:34

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:54:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:54:40
Data point term sent to Coder	System	16 Oct 2020 15:53:25
User entered 'CHRONIC JOINT PAIN'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:56

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1990'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:56

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:56

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:56

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:56

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:52:56

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1990'	System	16 Oct 2020 15:52:56

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1990'	System	16 Oct 2020 15:52:56

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:52:56

US3172374

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:52:56

US3172374

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 15:54:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 15:54:39
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 15:53:27
User entered 'ANXIETY'	Mariete Rendon (b) (4)	16 Oct 2020 15:53:23
	(b) (4)	

US3172374

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1999'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:53:23

US3172374

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:53:23

US3172374

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:53:23

US3172374

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:53:23

US3172374

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:53:23

US3172374

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1999'	System	16 Oct 2020 15:53:23

US3172374

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1999'	System	16 Oct 2020 15:53:23

US3172374

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:53:23

US3172374

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:53:23

US3172374

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 15:55:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 15:55:27
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 15:54:27
User entered 'DEPRESSION'	Mariete Rendon (b) (4)	16 Oct 2020 15:54:04
	(b) (4)	

US3172374

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'UN UNK 1990'	Mariete Rendon (b) (4)	16 Oct 2020 15:54:04
	(b) (4)	

US3172374

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	16 Oct 2020 15:54:04
	(b) (4)	

US3172374

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:54:04

US3172374

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:54:04

US3172374

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:54:04

US3172374

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1990'	System	16 Oct 2020 15:54:04

US3172374

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1990'	System	16 Oct 2020 15:54:04

US3172374

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:54:04

US3172374

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:54:04

US3172374

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 15:55:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 15:55:41
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 15:54:28
User entered 'INSOMNIA'	Mariete Rendon (b) (4)	16 Oct 2020 15:54:17
	(b) (4)	

US3172374

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1990'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:54:17

US3172374

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	16 Oct 2020 15:54:17
	(b) (4)	

US3172374

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:54:17

US3172374

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:54:17

US3172374

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:54:17

US3172374

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1990'	System	16 Oct 2020 15:54:17

US3172374

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1990'	System	16 Oct 2020 15:54:17

US3172374

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:54:17

US3172374

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:54:17

US3172374

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:21:51
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 21:36:54
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:12:07
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:56:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:56:22
Data point term sent to Coder	System	16 Oct 2020 15:55:29
User entered 'BIPOLAR DISORDER'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:55:11

US3172374

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 1990'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:55:11

US3172374

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:55:11

US3172374

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:55:11

US3172374

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:55:11

US3172374

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:55:11

US3172374

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 1990'	System	16 Oct 2020 15:55:11

US3172374

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '1990'	System	16 Oct 2020 15:55:11

US3172374

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:55:11

US3172374

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered empty.	System	16 Oct 2020 15:55:11

US3172374

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 20:39:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 20:39:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Right cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:58:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:58:37
Data point term sent to Coder	System	16 Oct 2020 15:57:32
User entered 'CATARACT RIGHT EYE SURGERY'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:36

US3172374

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:36

US3172374

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:36

US3172374

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:36

US3172374

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:36

US3172374

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:36

US3172374

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 2017'	System	16 Oct 2020 15:56:36

US3172374

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2017'	System	16 Oct 2020 15:56:36

US3172374

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 2017'	System	16 Oct 2020 15:56:36

US3172374

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2017'	System	16 Oct 2020 15:56:36

US3172374

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Penile therapeutic procedures, PT: Penile prosthesis insertion, LLT: Penile implant - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 15:58:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 15:58:36
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 15:57:34
User entered 'PENILE IMPLANT'	Mariete Rendon (b) (4)	16 Oct 2020 15:56:55
	(b) (4)	

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Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 2009'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:55

US3172374

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:55

US3172374

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:55

US3172374

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN UNK 2009'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:55

US3172374

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:56:55

US3172374

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 2009'	System	16 Oct 2020 15:56:55

US3172374

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2009'	System	16 Oct 2020 15:56:55

US3172374

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Jan 2009'	System	16 Oct 2020 15:56:55

US3172374

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2009'	System	16 Oct 2020 15:56:55

US3172374

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Toe amputation, LLT: Toe amputation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 12:53:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 12:53:46
Data point term sent to Coder	System	16 Oct 2020 15:58:37
User entered 'LEFT FOOT 3RD TOE AMPUTATION DUE TO PHYSICAL TRAUMA SURGERY'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:08

US3172374

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN Apr 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:08

US3172374

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:08

US3172374

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:08

US3172374

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN Apr 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:08

US3172374

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:08

US3172374

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Apr 2020'	System	16 Oct 2020 15:58:08

US3172374

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2020'	System	16 Oct 2020 15:58:08

US3172374

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Apr 2020'	System	16 Oct 2020 15:58:08

US3172374

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2020'	System	16 Oct 2020 15:58:08

US3172374

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Injury, LLT: Trauma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:56:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:56:06
Data point term sent to Coder	System	16 Oct 2020 15:58:37
User entered 'pPHYSICAL tRAUMA'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:25

US3172374

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN Apr 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:25

US3172374

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:25

US3172374

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 15:58:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 15:58:34
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:34
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 15:58:25
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:25

US3172374

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN Apr 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:34
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:25

US3172374

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:58:25

US3172374

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Apr 2020'	System	16 Oct 2020 15:58:25

US3172374

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2020'	System	16 Oct 2020 15:58:25

US3172374

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Apr 2020'	System	16 Oct 2020 15:58:34
User entered empty.	System	16 Oct 2020 15:58:25

US3172374

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2020'	System	16 Oct 2020 15:58:34
User entered empty.	System	16 Oct 2020 15:58:25

US3172374

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:30:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Localised infection, LLT: Foot infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:00:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:00:31
Data point term sent to Coder	System	16 Oct 2020 15:59:38
User entered 'LEFT FOOT INFECTION'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:59:24

US3172374

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN Apr 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:59:24

US3172374

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:59:24

US3172374

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:30:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:59:24

US3172374

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'UN Apr 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:59:24

US3172374

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:30:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:59:24

US3172374

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Apr 2020'	System	16 Oct 2020 15:59:24

US3172374

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2020'	System	16 Oct 2020 15:59:24

US3172374

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'Apr 2020'	System	16 Oct 2020 15:59:24

US3172374

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '2020'	System	16 Oct 2020 15:59:24

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '08:38'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '16 Oct 2020 08:38'	System	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '171.6' cm	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36
DataPoint set to visible.	System	16 Oct 2020 15:28:33

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '71.0' kg	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36
DataPoint set to visible.	System	16 Oct 2020 15:28:33

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered '24.11148'	System	16 Oct 2020 15:33:36
DataPoint set to visible.	System	16 Oct 2020 15:28:33

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'kg/m2'	System	16 Oct 2020 15:33:36
DataPoint set to visible.	System	16 Oct 2020 15:28:33

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'bpm'	System	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'breaths/min'	System	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'mmHg'	System	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User entered 'mmHg'	System	16 Oct 2020 15:33:36

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59

US3172374

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59

US3172374

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	16 Oct 2020 15:34:28
	(b) (4)	

US3172374

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	16 Oct 2020 15:34:28
	(b) (4)	

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

[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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

[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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'NOT WORKING'	Mariete Rendon (b) (4)	16 Oct 2020 15:35:35
	(b) (4)	

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	16 Oct 2020 15:35:35
	(b) (4)	

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

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)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:54:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:35

US3172374

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:54

US3172374

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:35:54

US3172374

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4)	16 Oct 2020 15:35:54
	(b) (4)	

US3172374

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'VISIT1'	System	16 Oct 2020 15:35:54

US3172374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 14:28:51

US3172374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:31

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '145124'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 14:28:51

US3172374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:31

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 14:28:51

US3172374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:31

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:02

US3172374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:31

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:02

US3172374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:31

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:02

US3172374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:02

US3172374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:02

US3172374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:31

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:02
DataPoint set to visible.	System	16 Oct 2020 15:28:24

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '08:28'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '16 Oct 2020 08:28'	System	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '37.2' C	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '79'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'bpm'	System	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'breaths/min'	System	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '98'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'mmHg'	System	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:40:16
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ABNORMAL, NCS' (Site from System).	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:12:07
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Oct 2020 16:11:38
User entered '55'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'mmHg'	System	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '11:48'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '16 Oct 2020 11:48'	System	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '36.5' C	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '79'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'bpm'	System	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'breaths/min'	System	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '138'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'mmHg'	System	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '70'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'mmHg'	System	16 Oct 2020 16:11:38

US3172374

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:22

US3172374

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:22

US3172374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:29:06

US3172374

Folder: Visit 1 Day 1

Form: Exposure

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If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:29:06

US3172374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:29:06

US3172374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 15:29:06

US3172374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '16 Oct 2020'	Mariete Rendon (b) (4)	16 Oct 2020 15:29:06
	(b) (4)	

US3172374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '11:18'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:29:06

US3172374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '16 Oct 2020 11:18'	System	16 Oct 2020 15:29:06

US3172374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:29:06

US3172374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'ONCE'	System	16 Oct 2020 15:29:06

US3172374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 15:29:06

US3172374

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:57

US3172374

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:57

US3172374

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '10:55'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:37:57

US3172374

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '16 Oct 2020 10:55'	System	16 Oct 2020 15:37:57

US3172374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:30:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:38:14

US3172374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:38:14

US3172374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:38:14

US3172374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '10:58'	Mariete Rendon (b) (4)	16 Oct 2020 15:38:14
	(b) (4)	

US3172374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '16 Oct 2020 10:58'	System	16 Oct 2020 15:38:14

US3172374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:38:14

US3172374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 15:38:14

US3172374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	16 Oct 2020 15:38:14
	(b) (4)	

US3172374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered empty.	System	16 Oct 2020 15:38:14

US3172374

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Oct 2020 19:59:55
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:00:08

US3172374

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '1'	System	23 Oct 2020 19:59:55
User entered empty.	System	16 Oct 2020 16:00:08

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:54:42', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4511e3bf-c766-436b-8f04-771421ead1c6' User entered 'Yes (Y)'	System	16 Oct 2020 15:55:38
	System	16 Oct 2020 15:55:38

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:55:25', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4511e3bf-c766-436b-8f04-771421ead1c6' User entered '97.7'	System	16 Oct 2020 15:55:38
	System	16 Oct 2020 15:55:38

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:55:32', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4511e3bf-c766-436b-8f04-771421ead1c6' User entered 'No (N)'	System	16 Oct 2020 15:55:38
	System	16 Oct 2020 15:55:38

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:55:36', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4511e3bf-c766-436b-8f04-771421ead1c6' User entered '16 Oct 2020 11:55'	System	16 Oct 2020 15:55:38
	System	16 Oct 2020 15:55:38

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Oct 2020 11:38'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Oct 2020 14:08'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Oct 2020 15:03'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 2'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:39:41', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5a3d65cb-665d-4b3e-8783-d9073a2a28f6' User entered 'Yes (Y)'	System	17 Oct 2020 23:42:42
	System	17 Oct 2020 23:42:42

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:42:27', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5a3d65cb-665d-4b3e-8783-d9073a2a28f6' User entered '93.9'	System	17 Oct 2020 23:42:42
	System	17 Oct 2020 23:42:42

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:42:31', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5a3d65cb-665d-4b3e-8783-d9073a2a28f6' User entered 'No (N)'	System	17 Oct 2020 23:42:42
	System	17 Oct 2020 23:42:42

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:42:37', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5a3d65cb-665d-4b3e-8783-d9073a2a28f6' User entered '17 Oct 2020 19:42'	System	17 Oct 2020 23:42:42
	System	17 Oct 2020 23:42:42

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 3'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:37:31', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '8e670161-75c2-41c9-89eb-2b4f476ea067'	System	18 Oct 2020 22:40:45
User entered 'Yes (Y)'	System	18 Oct 2020 22:40:45

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:40:34', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '8e670161-75c2-41c9-89eb-2b4f476ea067' User entered '97.6'	System	18 Oct 2020 22:40:45
	System	18 Oct 2020 22:40:45

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:40:39', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '8e670161-75c2-41c9-89eb-2b4f476ea067'	System	18 Oct 2020 22:40:45
User entered 'No (N)'	System	18 Oct 2020 22:40:45

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:40:42', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '8e670161-75c2-41c9-89eb-2b4f476ea067'	System	18 Oct 2020 22:40:45
User entered '18 Oct 2020 18:40'	System	18 Oct 2020 22:40:45

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 4'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:16:16', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '27d50e70-74d1-48b3-9803-6ccff7cf77b5' User entered 'Yes (Y)'	System	19 Oct 2020 21:17:44
	System	19 Oct 2020 21:17:44

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:17:29', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '27d50e70-74d1-48b3-9803-6ccff7cf77b5' User entered '96.8'	System	19 Oct 2020 21:17:44
	System	19 Oct 2020 21:17:44

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:17:35', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '27d50e70-74d1-48b3-9803-6ccff7cf77b5'	System	19 Oct 2020 21:17:44
User entered 'No (N)'	System	19 Oct 2020 21:17:44

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:17:42', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '27d50e70-74d1-48b3-9803-6ccff7cf77b5' User entered '19 Oct 2020 17:17'	System	19 Oct 2020 21:17:44
	System	19 Oct 2020 21:17:44

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 5'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:52:18', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5d348e33-9636-4ab5-ab04-c94420abc91d' User entered 'Yes (Y)'	System	21 Oct 2020 02:53:44
	System	21 Oct 2020 02:53:44

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:53:32', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5d348e33-9636-4ab5-ab04-c94420abc91d' User entered '97.2'	System	21 Oct 2020 02:53:44
	System	21 Oct 2020 02:53:44

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:53:36', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5d348e33-9636-4ab5-ab04-c94420abc91d' User entered 'No (N)'	System	21 Oct 2020 02:53:44
	System	21 Oct 2020 02:53:44

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:53:41', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5d348e33-9636-4ab5-ab04-c94420abc91d' User entered '20 Oct 2020 22:53'	System	21 Oct 2020 02:53:44
	System	21 Oct 2020 02:53:44

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 6'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:04:40', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd36e8a35-f1fc-4561-8ffb-76a86adb3b67' User entered 'Yes (Y)'	System	22 Oct 2020 00:08:43
	System	22 Oct 2020 00:08:43

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:08:33', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd36e8a35-f1fc-4561-8ffb-76a86adb3b67' User entered '97.8'	System	22 Oct 2020 00:08:43
	System	22 Oct 2020 00:08:43

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:08:36', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd36e8a35-f1fc-4561-8ffb-76a86adb3b67'	System	22 Oct 2020 00:08:43
User entered 'No (N)'	System	22 Oct 2020 00:08:43

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:08:40', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd36e8a35-f1fc-4561-8ffb-76a86adb3b67' User entered '21 Oct 2020 20:08'	System	22 Oct 2020 00:08:43
	System	22 Oct 2020 00:08:43

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 7'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T17:58:27', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '97912f38-8d15-4b9c-bea4-0a399993594f' User entered 'Yes (Y)'	System	22 Oct 2020 22:00:42
	System	22 Oct 2020 22:00:42

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:00:31', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '97912f38-8d15-4b9c-bea4-0a399993594f' User entered '96.8'	System	22 Oct 2020 22:00:42
	System	22 Oct 2020 22:00:42

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:00:34', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '97912f38-8d15-4b9c-bea4-0a399993594f' User entered 'No (N)'	System	22 Oct 2020 22:00:42
	System	22 Oct 2020 22:00:42

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:00:38', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '97912f38-8d15-4b9c-bea4-0a399993594f' User entered '22 Oct 2020 18:00'	System	22 Oct 2020 22:00:42
	System	22 Oct 2020 22:00:42

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:55:41', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '304816a7-0967-489b-8da7-49f4df6438a3' User entered 'None (1)'	System	16 Oct 2020 15:55:58
	System	16 Oct 2020 15:55:58

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:55:45', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '304816a7-0967-489b-8da7-49f4df6438a3' User entered 'No (N)'	System	16 Oct 2020 15:55:58
	System	16 Oct 2020 15:55:58

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:55:49', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '304816a7-0967-489b-8da7-49f4df6438a3' User entered 'No (N)'	System	16 Oct 2020 15:55:58
	System	16 Oct 2020 15:55:58

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:55:54', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '304816a7-0967-489b-8da7-49f4df6438a3' User entered 'None (1)'	System	16 Oct 2020 15:55:58
	System	16 Oct 2020 15:55:58

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:55:55', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '304816a7-0967-489b-8da7-49f4df6438a3' User entered '16 Oct 2020 11:55'	System	16 Oct 2020 15:55:58
	System	16 Oct 2020 15:55:58

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Oct 2020 11:38'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Oct 2020 14:08'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:24:36', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4bb9b2c7-47cb-44e5-8ba7-8e4058c2478a' User entered 'None (1)'	System	16 Oct 2020 21:25:05
	System	16 Oct 2020 21:25:05

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:24:43', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4bb9b2c7-47cb-44e5-8ba7-8e4058c2478a' User entered 'No (N)'	System	16 Oct 2020 21:25:05
	System	16 Oct 2020 21:25:05

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:24:48', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4bb9b2c7-47cb-44e5-8ba7-8e4058c2478a' User entered 'No (N)'	System	16 Oct 2020 21:25:05
	System	16 Oct 2020 21:25:05

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:24:52', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4bb9b2c7-47cb-44e5-8ba7-8e4058c2478a' User entered 'None (1)'	System	16 Oct 2020 21:25:05
	System	16 Oct 2020 21:25:05

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:25:02', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4bb9b2c7-47cb-44e5-8ba7-8e4058c2478a' User entered '16 Oct 2020 17:25'	System	16 Oct 2020 21:25:05
	System	16 Oct 2020 21:25:05

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Oct 2020 15:03'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 2'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:42:42', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd196d98a-fa4b-4122-b2ff-ea2d50a19b61'	System	17 Oct 2020 23:42:58
User entered 'None (1)'	System	17 Oct 2020 23:42:58

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:42:46', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd196d98a-fa4b-4122-b2ff-ea2d50a19b61'	System	17 Oct 2020 23:42:58
User entered 'No (N)'	System	17 Oct 2020 23:42:58

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:42:50', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd196d98a-fa4b-4122-b2ff-ea2d50a19b61' User entered 'No (N)'	System	17 Oct 2020 23:42:58
	System	17 Oct 2020 23:42:58

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:42:53', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd196d98a-fa4b-4122-b2ff-ea2d50a19b61'	System	17 Oct 2020 23:42:58
User entered 'None (1)'	System	17 Oct 2020 23:42:58

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:42:56', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd196d98a-fa4b-4122-b2ff-ea2d50a19b61' User entered '17 Oct 2020 19:42'	System	17 Oct 2020 23:42:58
	System	17 Oct 2020 23:42:58

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 3'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:40:49', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3de79e88-71f4-495d-83ec-ad9a032ea140' User entered 'None (1)'	System	18 Oct 2020 22:41:04
	System	18 Oct 2020 22:41:04

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:40:52', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3de79e88-71f4-495d-83ec-ad9a032ea140' User entered 'No (N)'	System	18 Oct 2020 22:41:04
	System	18 Oct 2020 22:41:04

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:40:56', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3de79e88-71f4-495d-83ec-ad9a032ea140' User entered 'No (N)'	System	18 Oct 2020 22:41:04
	System	18 Oct 2020 22:41:04

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:40:59', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3de79e88-71f4-495d-83ec-ad9a032ea140' User entered 'None (1)'	System	18 Oct 2020 22:41:04
	System	18 Oct 2020 22:41:04

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:41:02', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3de79e88-71f4-495d-83ec-ad9a032ea140' User entered '18 Oct 2020 18:41'	System	18 Oct 2020 22:41:04
	System	18 Oct 2020 22:41:04

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 4'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:17:48', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'da01765f-4e60-4a2e-bd6d-3dfe9b3ef619'	System	19 Oct 2020 21:18:05
User entered 'None (1)'	System	19 Oct 2020 21:18:05

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:17:52', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'da01765f-4e60-4a2e-bd6d-3dfe9b3ef619' User entered 'No (N)'	System	19 Oct 2020 21:18:05
	System	19 Oct 2020 21:18:05

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:17:55', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'da01765f-4e60-4a2e-bd6d-3dfe9b3ef619'	System	19 Oct 2020 21:18:05
User entered 'No (N)'	System	19 Oct 2020 21:18:05

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:17:58', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'da01765f-4e60-4a2e-bd6d-3dfe9b3ef619'	System	19 Oct 2020 21:18:05
User entered 'None (1)'	System	19 Oct 2020 21:18:05

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:18:02', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'da01765f-4e60-4a2e-bd6d-3dfe9b3ef619' User entered '19 Oct 2020 17:18'	System	19 Oct 2020 21:18:05
	System	19 Oct 2020 21:18:05

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 5'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:53:47', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'cf3382a4-a572-420c-b7d5-8624003c069e' User entered 'None (1)'	System	21 Oct 2020 02:54:02
	System	21 Oct 2020 02:54:02

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:53:50', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'cf3382a4-a572-420c-b7d5-8624003c069e' User entered 'No (N)'	System	21 Oct 2020 02:54:02
	System	21 Oct 2020 02:54:02

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:53:52', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'cf3382a4-a572-420c-b7d5-8624003c069e' User entered 'No (N)'	System	21 Oct 2020 02:54:02
	System	21 Oct 2020 02:54:02

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:53:55', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'cf3382a4-a572-420c-b7d5-8624003c069e' User entered 'None (1)'	System	21 Oct 2020 02:54:02
	System	21 Oct 2020 02:54:02

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:54:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'cf3382a4-a572-420c-b7d5-8624003c069e' User entered '20 Oct 2020 22:54'	System	21 Oct 2020 02:54:02
	System	21 Oct 2020 02:54:02

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 6'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:08:52', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd28f1d3a-8b44-49d7-8c3a-d82cd28d48fd' User entered 'None (1)'	System	22 Oct 2020 00:09:20
	System	22 Oct 2020 00:09:20

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:08:55', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd28f1d3a-8b44-49d7-8c3a-d82cd28d48fd' User entered 'No (N)'	System	22 Oct 2020 00:09:20
	System	22 Oct 2020 00:09:20

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:09:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd28f1d3a-8b44-49d7-8c3a-d82cd28d48fd' User entered 'No (N)'	System	22 Oct 2020 00:09:20
	System	22 Oct 2020 00:09:20

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:09:02', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd28f1d3a-8b44-49d7-8c3a-d82cd28d48fd' User entered 'None (1)'	System	22 Oct 2020 00:09:20
	System	22 Oct 2020 00:09:20

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:09:14', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd28f1d3a-8b44-49d7-8c3a-d82cd28d48fd' User entered '21 Oct 2020 20:09'	System	22 Oct 2020 00:09:20
	System	22 Oct 2020 00:09:20

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 7'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:00:45', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '929d523b-1a5d-4920-a22a-b7c2eedc4ced' User entered 'None (1)'	System	22 Oct 2020 22:01:04
	System	22 Oct 2020 22:01:04

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:00:49', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '929d523b-1a5d-4920-a22a-b7c2eedc4ced' User entered 'No (N)'	System	22 Oct 2020 22:01:04
	System	22 Oct 2020 22:01:04

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:00:52', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '929d523b-1a5d-4920-a22a-b7c2eedc4ced' User entered 'No (N)'	System	22 Oct 2020 22:01:04
	System	22 Oct 2020 22:01:04

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:00:56', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '929d523b-1a5d-4920-a22a-b7c2eedc4ced' User entered 'None (1)'	System	22 Oct 2020 22:01:04
	System	22 Oct 2020 22:01:04

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:00:59', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '929d523b-1a5d-4920-a22a-b7c2eedc4ced' User entered '22 Oct 2020 18:00'	System	22 Oct 2020 22:01:04
	System	22 Oct 2020 22:01:04

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:56:01', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '871032fd-b652-4a5f-b49c-c7a788e25889' User entered 'None (0)'	System	16 Oct 2020 15:56:26
	System	16 Oct 2020 15:56:26

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:56:05', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '871032fd-b652-4a5f-b49c-c7a788e25889' User entered 'None (0)'	System	16 Oct 2020 15:56:26
	System	16 Oct 2020 15:56:26

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:56:08', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '871032fd-b652-4a5f-b49c-c7a788e25889' User entered 'None (0)'	System	16 Oct 2020 15:56:26
	System	16 Oct 2020 15:56:26

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:56:11', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '871032fd-b652-4a5f-b49c-c7a788e25889' User entered 'None (0)'	System	16 Oct 2020 15:56:26
	System	16 Oct 2020 15:56:26

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:56:14', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '871032fd-b652-4a5f-b49c-c7a788e25889' User entered 'None (0)'	System	16 Oct 2020 15:56:26
	System	16 Oct 2020 15:56:26

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:56:16', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '871032fd-b652-4a5f-b49c-c7a788e25889' User entered 'None (0)'	System	16 Oct 2020 15:56:26
	System	16 Oct 2020 15:56:26

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:56:21', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '871032fd-b652-4a5f-b49c-c7a788e25889' User entered 'No (N)'	System	16 Oct 2020 15:56:26
	System	16 Oct 2020 15:56:26

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T11:56:22', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '871032fd-b652-4a5f-b49c-c7a788e25889' User entered '16 Oct 2020 11:56'	System	16 Oct 2020 15:56:26
	System	16 Oct 2020 15:56:26

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Oct 2020 11:38'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Oct 2020 14:08'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:23:42', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '011940f9-fd5e-4e47-860c-8d8e25884bdf' User entered 'None (0)'	System	16 Oct 2020 21:24:29
	System	16 Oct 2020 21:24:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:23:46', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '011940f9-fd5e-4e47-860c-8d8e25884bdf' User entered 'None (0)'	System	16 Oct 2020 21:24:29
	System	16 Oct 2020 21:24:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:23:50', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '011940f9-fd5e-4e47-860c-8d8e25884bdf' User entered 'None (0)'	System	16 Oct 2020 21:24:29
	System	16 Oct 2020 21:24:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:23:53', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '011940f9-fd5e-4e47-860c-8d8e25884bdf' User entered 'None (0)'	System	16 Oct 2020 21:24:29
	System	16 Oct 2020 21:24:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:23:57', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '011940f9-fd5e-4e47-860c-8d8e25884bdf' User entered 'None (0)'	System	16 Oct 2020 21:24:29
	System	16 Oct 2020 21:24:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:24:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '011940f9-fd5e-4e47-860c-8d8e25884bdf' User entered 'None (0)'	System	16 Oct 2020 21:24:29
	System	16 Oct 2020 21:24:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:24:10', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '011940f9-fd5e-4e47-860c-8d8e25884bdf' User entered 'No (N)'	System	16 Oct 2020 21:24:29
	System	16 Oct 2020 21:24:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-16T17:24:25', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '011940f9-fd5e-4e47-860c-8d8e25884bdf' User entered '16 Oct 2020 17:24'	System	16 Oct 2020 21:24:29
	System	16 Oct 2020 21:24:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Oct 2020 15:03'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 2'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:43:03', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'eaf98ba9-4017-42d8-9c00-cd9f4e2d5b26' User entered 'None (0)'	System	17 Oct 2020 23:43:39
	System	17 Oct 2020 23:43:39

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:43:06', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'eaf98ba9-4017-42d8-9c00-cd9f4e2d5b26' User entered 'None (0)'	System	17 Oct 2020 23:43:39
	System	17 Oct 2020 23:43:39

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:43:09', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'eaf98ba9-4017-42d8-9c00-cd9f4e2d5b26' User entered 'None (0)'	System	17 Oct 2020 23:43:39
	System	17 Oct 2020 23:43:39

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:43:13', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'eaf98ba9-4017-42d8-9c00-cd9f4e2d5b26' User entered 'None (0)'	System	17 Oct 2020 23:43:39
	System	17 Oct 2020 23:43:39

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:43:16', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'eaf98ba9-4017-42d8-9c00-cd9f4e2d5b26' User entered 'None (0)'	System	17 Oct 2020 23:43:39
	System	17 Oct 2020 23:43:39

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:43:19', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'eaf98ba9-4017-42d8-9c00-cd9f4e2d5b26' User entered 'None (0)'	System	17 Oct 2020 23:43:39
	System	17 Oct 2020 23:43:39

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:43:24', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'eaf98ba9-4017-42d8-9c00-cd9f4e2d5b26' User entered 'No (N)'	System	17 Oct 2020 23:43:39
	System	17 Oct 2020 23:43:39

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-17T19:43:27', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'eaf98ba9-4017-42d8-9c00-cd9f4e2d5b26' User entered '17 Oct 2020 19:43'	System	17 Oct 2020 23:43:39
	System	17 Oct 2020 23:43:39

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 3'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:41:07', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e2716953-70a5-4e1c-a72b-44d44d6eee61' User entered 'None (0)'	System	18 Oct 2020 22:41:29
	System	18 Oct 2020 22:41:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:41:10', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e2716953-70a5-4e1c-a72b-44d44d6eee61' User entered 'None (0)'	System	18 Oct 2020 22:41:29
	System	18 Oct 2020 22:41:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:41:12', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e2716953-70a5-4e1c-a72b-44d44d6eee61' User entered 'None (0)'	System	18 Oct 2020 22:41:29
	System	18 Oct 2020 22:41:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:41:13', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e2716953-70a5-4e1c-a72b-44d44d6eee61' User entered 'None (0)'	System	18 Oct 2020 22:41:29
	System	18 Oct 2020 22:41:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:41:15', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e2716953-70a5-4e1c-a72b-44d44d6eee61' User entered 'None (0)'	System	18 Oct 2020 22:41:29
	System	18 Oct 2020 22:41:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:41:19', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e2716953-70a5-4e1c-a72b-44d44d6eee61' User entered 'None (0)'	System	18 Oct 2020 22:41:29
	System	18 Oct 2020 22:41:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:41:22', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e2716953-70a5-4e1c-a72b-44d44d6eee61' User entered 'No (N)'	System	18 Oct 2020 22:41:29
	System	18 Oct 2020 22:41:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-18T18:41:25', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e2716953-70a5-4e1c-a72b-44d44d6eee61' User entered '18 Oct 2020 18:41'	System	18 Oct 2020 22:41:29
	System	18 Oct 2020 22:41:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 4'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:18:07', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5900b18e-e817-4548-8b3d-371ecc44136a' User entered 'None (0)'	System	19 Oct 2020 21:18:37
	System	19 Oct 2020 21:18:37

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:18:11', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5900b18e-e817-4548-8b3d-371ecc44136a' User entered 'None (0)'	System	19 Oct 2020 21:18:37
	System	19 Oct 2020 21:18:37

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:18:15', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5900b18e-e817-4548-8b3d-371ecc44136a' User entered 'None (0)'	System	19 Oct 2020 21:18:37
	System	19 Oct 2020 21:18:37

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:18:18', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5900b18e-e817-4548-8b3d-371ecc44136a' User entered 'None (0)'	System	19 Oct 2020 21:18:37
	System	19 Oct 2020 21:18:37

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:18:21', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5900b18e-e817-4548-8b3d-371ecc44136a' User entered 'None (0)'	System	19 Oct 2020 21:18:37
	System	19 Oct 2020 21:18:37

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:18:24', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5900b18e-e817-4548-8b3d-371ecc44136a' User entered 'None (0)'	System	19 Oct 2020 21:18:37
	System	19 Oct 2020 21:18:37

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:18:29', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5900b18e-e817-4548-8b3d-371ecc44136a' User entered 'No (N)'	System	19 Oct 2020 21:18:37
	System	19 Oct 2020 21:18:37

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-19T17:18:31', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '5900b18e-e817-4548-8b3d-371ecc44136a' User entered '19 Oct 2020 17:18'	System	19 Oct 2020 21:18:37
	System	19 Oct 2020 21:18:37

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 5'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:54:05', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b7d4d0ba-3dd0-4e61-885b-25f3caa3729b' User entered 'None (0)'	System	21 Oct 2020 02:54:24
	System	21 Oct 2020 02:54:24

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:54:07', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b7d4d0ba-3dd0-4e61-885b-25f3caa3729b' User entered 'None (0)'	System	21 Oct 2020 02:54:24
	System	21 Oct 2020 02:54:24

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:54:09', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b7d4d0ba-3dd0-4e61-885b-25f3caa3729b' User entered 'None (0)'	System	21 Oct 2020 02:54:24
	System	21 Oct 2020 02:54:24

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:54:11', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b7d4d0ba-3dd0-4e61-885b-25f3caa3729b' User entered 'None (0)'	System	21 Oct 2020 02:54:24
	System	21 Oct 2020 02:54:24

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:54:13', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b7d4d0ba-3dd0-4e61-885b-25f3caa3729b' User entered 'None (0)'	System	21 Oct 2020 02:54:24
	System	21 Oct 2020 02:54:24

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:54:14', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b7d4d0ba-3dd0-4e61-885b-25f3caa3729b' User entered 'None (0)'	System	21 Oct 2020 02:54:24
	System	21 Oct 2020 02:54:24

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:54:19', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b7d4d0ba-3dd0-4e61-885b-25f3caa3729b' User entered 'No (N)'	System	21 Oct 2020 02:54:24
	System	21 Oct 2020 02:54:24

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-20T22:54:22', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b7d4d0ba-3dd0-4e61-885b-25f3caa3729b' User entered '20 Oct 2020 22:54'	System	21 Oct 2020 02:54:24
	System	21 Oct 2020 02:54:24

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 6'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:09:33', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '036486cd-36af-49d7-bc48-6fff1643207a' User entered 'None (0)'	System	22 Oct 2020 00:10:08
	System	22 Oct 2020 00:10:08

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:09:36', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '036486cd-36af-49d7-bc48-6fff1643207a' User entered 'None (0)'	System	22 Oct 2020 00:10:08
	System	22 Oct 2020 00:10:08

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:09:41', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '036486cd-36af-49d7-bc48-6fff1643207a' User entered 'None (0)'	System	22 Oct 2020 00:10:08
	System	22 Oct 2020 00:10:08

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:09:43', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '036486cd-36af-49d7-bc48-6fff1643207a' User entered 'None (0)'	System	22 Oct 2020 00:10:08
	System	22 Oct 2020 00:10:08

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:09:45', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '036486cd-36af-49d7-bc48-6fff1643207a' User entered 'None (0)'	System	22 Oct 2020 00:10:08
	System	22 Oct 2020 00:10:08

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:09:48', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '036486cd-36af-49d7-bc48-6fff1643207a' User entered 'None (0)'	System	22 Oct 2020 00:10:08
	System	22 Oct 2020 00:10:08

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:09:50', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '036486cd-36af-49d7-bc48-6fff1643207a' User entered 'No (N)'	System	22 Oct 2020 00:10:08
	System	22 Oct 2020 00:10:08

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-21T20:10:03', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '036486cd-36af-49d7-bc48-6fff1643207a' User entered '21 Oct 2020 20:10'	System	22 Oct 2020 00:10:08
	System	22 Oct 2020 00:10:08

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	16 Oct 2020 15:29:06
User entered 'Day 7'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:01:07', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '806e9313-4969-472b-9837-85a4b4358efe' User entered 'None (0)'	System	22 Oct 2020 22:01:29
	System	22 Oct 2020 22:01:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:01:10', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '806e9313-4969-472b-9837-85a4b4358efe' User entered 'None (0)'	System	22 Oct 2020 22:01:29
	System	22 Oct 2020 22:01:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:01:13', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '806e9313-4969-472b-9837-85a4b4358efe' User entered 'None (0)'	System	22 Oct 2020 22:01:29
	System	22 Oct 2020 22:01:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:01:15', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '806e9313-4969-472b-9837-85a4b4358efe' User entered 'None (0)'	System	22 Oct 2020 22:01:29
	System	22 Oct 2020 22:01:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:01:18', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '806e9313-4969-472b-9837-85a4b4358efe' User entered 'None (0)'	System	22 Oct 2020 22:01:29
	System	22 Oct 2020 22:01:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:01:20', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '806e9313-4969-472b-9837-85a4b4358efe' User entered 'None (0)'	System	22 Oct 2020 22:01:29
	System	22 Oct 2020 22:01:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:01:24', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '806e9313-4969-472b-9837-85a4b4358efe' User entered 'No (N)'	System	22 Oct 2020 22:01:29
	System	22 Oct 2020 22:01:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-10-22T18:01:27', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '806e9313-4969-472b-9837-85a4b4358efe' User entered '22 Oct 2020 18:01'	System	22 Oct 2020 22:01:29
	System	22 Oct 2020 22:01:29

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 15:29:06

US3172374

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 15:29:06

US3172374

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Oct 2020 20:00:25

US3172374

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '23 Oct 2020'	Jessie Downs (b) (4)	23 Oct 2020 20:00:25
	(b) (4)	

US3172374

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	23 Oct 2020 20:00:25

US3172374

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Oct 2020 20:00:25

US3172374

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Nov 2020 14:04:23
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Oct 2020 20:00:55
	(b) (4)	

US3172374

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '1'	System	02 Nov 2020 14:04:23
User entered empty.	System	23 Oct 2020 20:00:55

US3172374

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Nov 2020 14:04:41

US3172374

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '30 Oct 2020'	Jessie Downs (b) (4)	02 Nov 2020 14:04:41
	(b) (4)	

US3172374

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	02 Nov 2020 14:04:41

US3172374

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Nov 2020 14:04:41

US3172374

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	09 Nov 2020 21:28:25
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	02 Nov 2020 14:04:47
	(b) (4)	

US3172374

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '1'	System	09 Nov 2020 21:28:25
User entered empty.	System	02 Nov 2020 14:04:47

US3172374

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 21:28:52

US3172374

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '09 Nov 2020'	Jessie Downs (b) (4)	09 Nov 2020 21:28:52
	(b) (4)	

US3172374

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 21:28:52

US3172374

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 21:28:52

US3172374

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 21:29:20

US3172374

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'I'	System	09 Nov 2020 21:29:20

US3172374

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:45:39

US3172374

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '13 Nov 2020'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:45:39

US3172374

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:45:39

US3172374

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'VISIT2'	System	13 Nov 2020 18:45:39

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '13 Nov 2020'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '09:51'	Jessie Downs (b) (4)	13 Nov 2020 18:46:25
	(b) (4)	

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '13 Nov 2020 09:51'	System	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '37.1' C	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '95'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'bpm'	System	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'breaths/min'	System	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '125'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'mmHg'	System	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '74'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'mmHg'	System	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 19:09:19
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '13 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Nov 2020 19:09:19
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	13 Nov 2020 18:46:25
	(b) (4)	

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '12:43' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 19:09:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '13 Nov 2020 12:43'	System	13 Nov 2020 19:09:19
User entered empty.	System	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '37.1' C reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 19:09:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 19:09:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '79' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 19:09:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'bpm'	System	13 Nov 2020 19:09:19
User entered empty.	System	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 19:09:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'breaths/min'	System	13 Nov 2020 19:09:19
User entered empty.	System	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '136' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 19:09:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'mmHg'	System	13 Nov 2020 19:09:19
User entered empty.	System	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '73' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 19:09:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'mmHg'	System	13 Nov 2020 19:09:19
User entered empty.	System	13 Nov 2020 18:46:25

US3172374

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:35

US3172374

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '13 Nov 2020'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:35

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:17:56

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:17:56

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:17:56

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'MRNA-1273 OR PLACEBO'	System	13 Nov 2020 17:17:56

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '13 Nov 2020'	Jessie Downs (b) (4)	13 Nov 2020 17:17:56
	(b) (4)	

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '12:13'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:17:56

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '13 Nov 2020 12:13'	System	13 Nov 2020 17:17:56

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:17:56

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'ONCE'	System	13 Nov 2020 17:17:56

US3172374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'INTRAMUSCULAR'	System	13 Nov 2020 17:17:56

US3172374

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:54

US3172374

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '13 Nov 2020'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:54

US3172374

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '11:30'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:46:54

US3172374

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '13 Nov 2020 11:30'	System	13 Nov 2020 18:46:54

US3172374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:30:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '13 Nov 2020'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:47:10

US3172374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:47:10

US3172374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:47:10

US3172374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '11:32'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:47:10

US3172374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '13 Nov 2020 11:32'	System	13 Nov 2020 18:47:10

US3172374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:47:10

US3172374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:47:10

US3172374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:47:10

US3172374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered empty.	System	13 Nov 2020 18:47:10

US3172374

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:47:14

US3172374

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'I'	System	13 Nov 2020 18:47:14

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:42:18', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '9f4fedcb-6c17-4c98-a4b2-4916714c1690' User entered 'Yes (Y)'	System	13 Nov 2020 17:43:39
	System	13 Nov 2020 17:43:39

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:43:21', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '9f4fedcb-6c17-4c98-a4b2-4916714c1690' User entered '98.8'	System	13 Nov 2020 17:43:39
	System	13 Nov 2020 17:43:39

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:43:32', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '9f4fedcb-6c17-4c98-a4b2-4916714c1690' User entered 'No (N)'	System	13 Nov 2020 17:43:39
	System	13 Nov 2020 17:43:39

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:43:36', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '9f4fedcb-6c17-4c98-a4b2-4916714c1690' User entered '13 Nov 2020 12:43'	System	13 Nov 2020 17:43:39
	System	13 Nov 2020 17:43:39

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '13 Nov 2020 12:33'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '13 Nov 2020 15:03'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 1, after vaccination (at home)'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:46:10', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '874200be-4d31-4b32-a282-976fe29fe7cb' User entered 'Yes (Y)'	System	13 Nov 2020 22:47:26
	System	13 Nov 2020 22:47:26

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:47:13', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '874200be-4d31-4b32-a282-976fe29fe7cb' User entered '96.4'	System	13 Nov 2020 22:47:26
	System	13 Nov 2020 22:47:26

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:47:18', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '874200be-4d31-4b32-a282-976fe29fe7cb' User entered 'No (N)'	System	13 Nov 2020 22:47:26
	System	13 Nov 2020 22:47:26

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:47:24', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '874200be-4d31-4b32-a282-976fe29fe7cb' User entered '13 Nov 2020 17:47'	System	13 Nov 2020 22:47:26
	System	13 Nov 2020 22:47:26

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '13 Nov 2020 15:58'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '14 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 2'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:40:42', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '159796b3-db69-4d22-b459-a9764697b95c' User entered 'Yes (Y)'	System	14 Nov 2020 23:42:29
	System	14 Nov 2020 23:42:29

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:41:53', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '159796b3-db69-4d22-b459-a9764697b95c' User entered '98.1'	System	14 Nov 2020 23:42:29
	System	14 Nov 2020 23:42:29

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:42:21', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '159796b3-db69-4d22-b459-a9764697b95c' User entered 'No (N)'	System	14 Nov 2020 23:42:29
	System	14 Nov 2020 23:42:29

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:42:27', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '159796b3-db69-4d22-b459-a9764697b95c' User entered '14 Nov 2020 18:42'	System	14 Nov 2020 23:42:29
	System	14 Nov 2020 23:42:29

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '14 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '15 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 3'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '15 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 4'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:03:10', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '17477ac1-3767-43dd-94e7-0f884a1f6d0a' User entered 'Yes (Y)'	System	17 Nov 2020 00:03:59
	System	17 Nov 2020 00:03:59

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:03:50', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '17477ac1-3767-43dd-94e7-0f884a1f6d0a' User entered '94.1'	System	17 Nov 2020 00:03:59
	System	17 Nov 2020 00:03:59

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:03:54', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '17477ac1-3767-43dd-94e7-0f884a1f6d0a' User entered 'No (N)'	System	17 Nov 2020 00:03:59
	System	17 Nov 2020 00:03:59

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:03:56', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '17477ac1-3767-43dd-94e7-0f884a1f6d0a' User entered '16 Nov 2020 19:03'	System	17 Nov 2020 00:03:59
	System	17 Nov 2020 00:03:59

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 5'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:39:04', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '059231bf-d438-457d-97be-c01e7d34eccc' User entered 'Yes (Y)'	System	18 Nov 2020 00:40:04
	System	18 Nov 2020 00:40:04

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:39:53', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '059231bf-d438-457d-97be-c01e7d34eccc' User entered '93.1'	System	18 Nov 2020 00:40:04
	System	18 Nov 2020 00:40:04

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:39:57', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '059231bf-d438-457d-97be-c01e7d34eccc' User entered 'No (N)'	System	18 Nov 2020 00:40:04
	System	18 Nov 2020 00:40:04

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '059231bf-d438-457d-97be-c01e7d34eccc' User entered '17 Nov 2020 19:40'	System	18 Nov 2020 00:40:04
	System	18 Nov 2020 00:40:04

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 6'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:22:48', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e6d44ab3-b7a2-4f26-845b-0adaef33606a' User entered 'Yes (Y)'	System	18 Nov 2020 22:24:20
	System	18 Nov 2020 22:24:20

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:05', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e6d44ab3-b7a2-4f26-845b-0adaef33606a' User entered '97.6'	System	18 Nov 2020 22:24:20
	System	18 Nov 2020 22:24:20

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:15', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e6d44ab3-b7a2-4f26-845b-0adaef33606a' User entered 'No (N)'	System	18 Nov 2020 22:24:20
	System	18 Nov 2020 22:24:20

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:18', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e6d44ab3-b7a2-4f26-845b-0adaef33606a' User entered '18 Nov 2020 17:24'	System	18 Nov 2020 22:24:20
	System	18 Nov 2020 22:24:20

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 7'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:41:59', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '16199eef-1238-415c-b391-a9b999cf9b01' User entered 'Yes (Y)'	System	20 Nov 2020 03:42:17
	System	20 Nov 2020 03:42:17

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:08', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '16199eef-1238-415c-b391-a9b999cf9b01' User entered '97.9'	System	20 Nov 2020 03:42:17
	System	20 Nov 2020 03:42:17

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:11', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '16199eef-1238-415c-b391-a9b999cf9b01' User entered 'No (N)'	System	20 Nov 2020 03:42:17
	System	20 Nov 2020 03:42:17

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:14', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '16199eef-1238-415c-b391-a9b999cf9b01' User entered '19 Nov 2020 22:42'	System	20 Nov 2020 03:42:17
	System	20 Nov 2020 03:42:17

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '20 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:43:45', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e3170ece-9a20-4184-a9b9-205d14006ceb' User entered 'None (1)'	System	13 Nov 2020 17:44:12
	System	13 Nov 2020 17:44:12

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:43:52', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e3170ece-9a20-4184-a9b9-205d14006ceb' User entered 'No (N)'	System	13 Nov 2020 17:44:12
	System	13 Nov 2020 17:44:12

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:43:59', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e3170ece-9a20-4184-a9b9-205d14006ceb' User entered 'No (N)'	System	13 Nov 2020 17:44:12
	System	13 Nov 2020 17:44:12

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:44:05', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e3170ece-9a20-4184-a9b9-205d14006ceb' User entered 'None (1)'	System	13 Nov 2020 17:44:12
	System	13 Nov 2020 17:44:12

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:44:08', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e3170ece-9a20-4184-a9b9-205d14006ceb' User entered '13 Nov 2020 12:44'	System	13 Nov 2020 17:44:12
	System	13 Nov 2020 17:44:12

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '13 Nov 2020 12:33'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '13 Nov 2020 15:03'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 1, after vaccination (at home)'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:47:32', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '8fcf86da-0c39-4e1b-9f66-bd1cfdcf6bcf'	System	13 Nov 2020 22:47:58
User entered 'None (1)'	System	13 Nov 2020 22:47:58

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:47:45', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '8fcf86da-0c39-4e1b-9f66-bd1cfdcf6bcf'	System	13 Nov 2020 22:47:58
User entered 'No (N)'	System	13 Nov 2020 22:47:58

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:47:49', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '8fcf86da-0c39-4e1b-9f66-bd1cfdcf6bcf' User entered 'No (N)'	System	13 Nov 2020 22:47:58
	System	13 Nov 2020 22:47:58

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:47:52', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '8fcf86da-0c39-4e1b-9f66-bd1cfdcf6bcf'	System	13 Nov 2020 22:47:58
User entered 'None (1)'	System	13 Nov 2020 22:47:58

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:47:55', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '8fcf86da-0c39-4e1b-9f66-bd1cfdcf6bcf' User entered '13 Nov 2020 17:47'	System	13 Nov 2020 22:47:58
	System	13 Nov 2020 22:47:58

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '13 Nov 2020 15:58'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '14 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 2'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:42:33', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3ec63d7d-4afa-4570-9646-2563a084fc2b' User entered 'None (1)'	System	14 Nov 2020 23:42:46
	System	14 Nov 2020 23:42:46

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:42:36', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3ec63d7d-4afa-4570-9646-2563a084fc2b' User entered 'No (N)'	System	14 Nov 2020 23:42:46
	System	14 Nov 2020 23:42:46

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:42:39', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3ec63d7d-4afa-4570-9646-2563a084fc2b' User entered 'No (N)'	System	14 Nov 2020 23:42:46
	System	14 Nov 2020 23:42:46

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:42:41', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3ec63d7d-4afa-4570-9646-2563a084fc2b' User entered 'None (1)'	System	14 Nov 2020 23:42:46
	System	14 Nov 2020 23:42:46

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:42:44', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3ec63d7d-4afa-4570-9646-2563a084fc2b' User entered '14 Nov 2020 18:42'	System	14 Nov 2020 23:42:46
	System	14 Nov 2020 23:42:46

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '14 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '15 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 3'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '15 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 4'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:02', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4c65b5af-707a-436f-9ef8-799bb295c992'	System	17 Nov 2020 00:04:15
User entered 'None (1)'	System	17 Nov 2020 00:04:15

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:05', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4c65b5af-707a-436f-9ef8-799bb295c992'	System	17 Nov 2020 00:04:15
User entered 'No (N)'	System	17 Nov 2020 00:04:15

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:07', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4c65b5af-707a-436f-9ef8-799bb295c992'	System	17 Nov 2020 00:04:15
User entered 'No (N)'	System	17 Nov 2020 00:04:15

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:09', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4c65b5af-707a-436f-9ef8-799bb295c992'	System	17 Nov 2020 00:04:15
User entered 'None (1)'	System	17 Nov 2020 00:04:15

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:13', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4c65b5af-707a-436f-9ef8-799bb295c992'	System	17 Nov 2020 00:04:15
User entered '16 Nov 2020 19:04'	System	17 Nov 2020 00:04:15

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 5'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:06', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f2ad6f20-2b80-418b-a24d-be779cdd7a69'	System	18 Nov 2020 00:40:28
User entered 'None (1)'	System	18 Nov 2020 00:40:28

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:10', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f2ad6f20-2b80-418b-a24d-be779cdd7a69'	System	18 Nov 2020 00:40:28
User entered 'No (N)'	System	18 Nov 2020 00:40:28

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:19', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f2ad6f20-2b80-418b-a24d-be779cdd7a69' User entered 'No (N)'	System	18 Nov 2020 00:40:28
	System	18 Nov 2020 00:40:28

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:21', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f2ad6f20-2b80-418b-a24d-be779cdd7a69'	System	18 Nov 2020 00:40:28
User entered 'None (1)'	System	18 Nov 2020 00:40:28

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:24', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f2ad6f20-2b80-418b-a24d-be779cdd7a69' User entered '17 Nov 2020 19:40'	System	18 Nov 2020 00:40:28
	System	18 Nov 2020 00:40:28

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 6'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:23', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '30c805d5-b0d5-4c2d-a51f-076ede42589f' User entered 'None (1)'	System	18 Nov 2020 22:24:43
	System	18 Nov 2020 22:24:43

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:27', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '30c805d5-b0d5-4c2d-a51f-076ede42589f' User entered 'No (N)'	System	18 Nov 2020 22:24:43
	System	18 Nov 2020 22:24:43

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:29', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '30c805d5-b0d5-4c2d-a51f-076ede42589f' User entered 'No (N)'	System	18 Nov 2020 22:24:43
	System	18 Nov 2020 22:24:43

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:32', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '30c805d5-b0d5-4c2d-a51f-076ede42589f' User entered 'None (1)'	System	18 Nov 2020 22:24:43
	System	18 Nov 2020 22:24:43

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:38', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '30c805d5-b0d5-4c2d-a51f-076ede42589f' User entered '18 Nov 2020 17:24'	System	18 Nov 2020 22:24:43
	System	18 Nov 2020 22:24:43

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 7'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:18', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'a268282c-e1e2-40ae-a813-f845bb9c2a57'	System	20 Nov 2020 03:42:33
User entered 'None (1)'	System	20 Nov 2020 03:42:33

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:20', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'a268282c-e1e2-40ae-a813-f845bb9c2a57'	System	20 Nov 2020 03:42:33
User entered 'No (N)'	System	20 Nov 2020 03:42:33

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:22', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'a268282c-e1e2-40ae-a813-f845bb9c2a57'	System	20 Nov 2020 03:42:33
User entered 'No (N)'	System	20 Nov 2020 03:42:33

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:24', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'a268282c-e1e2-40ae-a813-f845bb9c2a57'	System	20 Nov 2020 03:42:33
User entered 'None (1)'	System	20 Nov 2020 03:42:33

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:29', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'a268282c-e1e2-40ae-a813-f845bb9c2a57' User entered '19 Nov 2020 22:42'	System	20 Nov 2020 03:42:33
	System	20 Nov 2020 03:42:33

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '20 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:44:14', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '642c02c0-dcd4-495f-b189-0c4d00ac2442' User entered 'None (0)'	System	13 Nov 2020 17:44:51
	System	13 Nov 2020 17:44:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:44:19', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '642c02c0-dcd4-495f-b189-0c4d00ac2442' User entered 'None (0)'	System	13 Nov 2020 17:44:51
	System	13 Nov 2020 17:44:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:44:31', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '642c02c0-dcd4-495f-b189-0c4d00ac2442' User entered 'None (0)'	System	13 Nov 2020 17:44:51
	System	13 Nov 2020 17:44:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:44:34', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '642c02c0-dcd4-495f-b189-0c4d00ac2442' User entered 'None (0)'	System	13 Nov 2020 17:44:51
	System	13 Nov 2020 17:44:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:44:38', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '642c02c0-dcd4-495f-b189-0c4d00ac2442' User entered 'None (0)'	System	13 Nov 2020 17:44:51
	System	13 Nov 2020 17:44:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:44:41', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '642c02c0-dcd4-495f-b189-0c4d00ac2442' User entered 'None (0)'	System	13 Nov 2020 17:44:51
	System	13 Nov 2020 17:44:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:44:45', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '642c02c0-dcd4-495f-b189-0c4d00ac2442' User entered 'No (N)'	System	13 Nov 2020 17:44:51
	System	13 Nov 2020 17:44:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T12:44:48', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '642c02c0-dcd4-495f-b189-0c4d00ac2442' User entered '13 Nov 2020 12:44'	System	13 Nov 2020 17:44:51
	System	13 Nov 2020 17:44:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '13 Nov 2020 12:33'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '13 Nov 2020 15:03'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 1, after vaccination (at home)'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:48:01', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '19b34803-d170-4069-ad0f-372d2f93b56b' User entered 'None (0)'	System	13 Nov 2020 22:48:25
	System	13 Nov 2020 22:48:25

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:48:04', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '19b34803-d170-4069-ad0f-372d2f93b56b' User entered 'None (0)'	System	13 Nov 2020 22:48:25
	System	13 Nov 2020 22:48:25

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:48:06', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '19b34803-d170-4069-ad0f-372d2f93b56b' User entered 'None (0)'	System	13 Nov 2020 22:48:25
	System	13 Nov 2020 22:48:25

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:48:09', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '19b34803-d170-4069-ad0f-372d2f93b56b' User entered 'None (0)'	System	13 Nov 2020 22:48:25
	System	13 Nov 2020 22:48:25

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:48:12', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '19b34803-d170-4069-ad0f-372d2f93b56b' User entered 'None (0)'	System	13 Nov 2020 22:48:25
	System	13 Nov 2020 22:48:25

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:48:15', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '19b34803-d170-4069-ad0f-372d2f93b56b' User entered 'None (0)'	System	13 Nov 2020 22:48:25
	System	13 Nov 2020 22:48:25

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:48:18', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '19b34803-d170-4069-ad0f-372d2f93b56b' User entered 'No (N)'	System	13 Nov 2020 22:48:25
	System	13 Nov 2020 22:48:25

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-13T17:48:22', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '19b34803-d170-4069-ad0f-372d2f93b56b' User entered '13 Nov 2020 17:48'	System	13 Nov 2020 22:48:25
	System	13 Nov 2020 22:48:25

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '13 Nov 2020 15:58'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '14 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 2'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:42:51', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '64f1eada-b1a5-4cf6-a02b-d277247891c3' User entered 'None (0)'	System	14 Nov 2020 23:43:17
	System	14 Nov 2020 23:43:17

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:42:55', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '64f1eada-b1a5-4cf6-a02b-d277247891c3' User entered 'None (0)'	System	14 Nov 2020 23:43:17
	System	14 Nov 2020 23:43:17

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:42:58', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '64f1eada-b1a5-4cf6-a02b-d277247891c3' User entered 'None (0)'	System	14 Nov 2020 23:43:17
	System	14 Nov 2020 23:43:17

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:43:02', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '64f1eada-b1a5-4cf6-a02b-d277247891c3' User entered 'None (0)'	System	14 Nov 2020 23:43:17
	System	14 Nov 2020 23:43:17

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:43:05', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '64f1eada-b1a5-4cf6-a02b-d277247891c3' User entered 'None (0)'	System	14 Nov 2020 23:43:17
	System	14 Nov 2020 23:43:17

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:43:08', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '64f1eada-b1a5-4cf6-a02b-d277247891c3' User entered 'None (0)'	System	14 Nov 2020 23:43:17
	System	14 Nov 2020 23:43:17

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:43:12', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '64f1eada-b1a5-4cf6-a02b-d277247891c3' User entered 'No (N)'	System	14 Nov 2020 23:43:17
	System	14 Nov 2020 23:43:17

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-14T18:43:15', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '64f1eada-b1a5-4cf6-a02b-d277247891c3' User entered '14 Nov 2020 18:43'	System	14 Nov 2020 23:43:17
	System	14 Nov 2020 23:43:17

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '14 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '15 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 3'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '15 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 4'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:22', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '55bd7402-c8be-4f68-9640-5f8ef4a205b4' User entered 'None (0)'	System	17 Nov 2020 00:04:48
	System	17 Nov 2020 00:04:48

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:24', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '55bd7402-c8be-4f68-9640-5f8ef4a205b4' User entered 'None (0)'	System	17 Nov 2020 00:04:48
	System	17 Nov 2020 00:04:48

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:26', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '55bd7402-c8be-4f68-9640-5f8ef4a205b4' User entered 'None (0)'	System	17 Nov 2020 00:04:48
	System	17 Nov 2020 00:04:48

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:28', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '55bd7402-c8be-4f68-9640-5f8ef4a205b4' User entered 'None (0)'	System	17 Nov 2020 00:04:48
	System	17 Nov 2020 00:04:48

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:33', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '55bd7402-c8be-4f68-9640-5f8ef4a205b4' User entered 'None (0)'	System	17 Nov 2020 00:04:48
	System	17 Nov 2020 00:04:48

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:37', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '55bd7402-c8be-4f68-9640-5f8ef4a205b4' User entered 'None (0)'	System	17 Nov 2020 00:04:48
	System	17 Nov 2020 00:04:48

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:43', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '55bd7402-c8be-4f68-9640-5f8ef4a205b4' User entered 'No (N)'	System	17 Nov 2020 00:04:48
	System	17 Nov 2020 00:04:48

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-16T19:04:46', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '55bd7402-c8be-4f68-9640-5f8ef4a205b4' User entered '16 Nov 2020 19:04'	System	17 Nov 2020 00:04:48
	System	17 Nov 2020 00:04:48

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '16 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 5'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:29', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f1bc8d04-f9df-4066-af07-52483d614033' User entered 'None (0)'	System	18 Nov 2020 00:40:51
	System	18 Nov 2020 00:40:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:32', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f1bc8d04-f9df-4066-af07-52483d614033' User entered 'None (0)'	System	18 Nov 2020 00:40:51
	System	18 Nov 2020 00:40:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:35', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f1bc8d04-f9df-4066-af07-52483d614033' User entered 'None (0)'	System	18 Nov 2020 00:40:51
	System	18 Nov 2020 00:40:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:37', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f1bc8d04-f9df-4066-af07-52483d614033' User entered 'None (0)'	System	18 Nov 2020 00:40:51
	System	18 Nov 2020 00:40:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:38', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f1bc8d04-f9df-4066-af07-52483d614033' User entered 'None (0)'	System	18 Nov 2020 00:40:51
	System	18 Nov 2020 00:40:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:40', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f1bc8d04-f9df-4066-af07-52483d614033' User entered 'None (0)'	System	18 Nov 2020 00:40:51
	System	18 Nov 2020 00:40:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:44', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f1bc8d04-f9df-4066-af07-52483d614033'	System	18 Nov 2020 00:40:51
User entered 'No (N)'	System	18 Nov 2020 00:40:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-17T19:40:47', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'f1bc8d04-f9df-4066-af07-52483d614033'	System	18 Nov 2020 00:40:51
User entered '17 Nov 2020 19:40'	System	18 Nov 2020 00:40:51

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '17 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 6'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:45', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ca05f635-6d01-4d8b-96bd-c90bdb078d02' User entered 'None (0)'	System	18 Nov 2020 22:25:11
	System	18 Nov 2020 22:25:11

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:48', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ca05f635-6d01-4d8b-96bd-c90bdb078d02' User entered 'None (0)'	System	18 Nov 2020 22:25:11
	System	18 Nov 2020 22:25:11

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:50', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ca05f635-6d01-4d8b-96bd-c90bdb078d02' User entered 'None (0)'	System	18 Nov 2020 22:25:11
	System	18 Nov 2020 22:25:11

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:52', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ca05f635-6d01-4d8b-96bd-c90bdb078d02' User entered 'None (0)'	System	18 Nov 2020 22:25:11
	System	18 Nov 2020 22:25:11

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:55', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ca05f635-6d01-4d8b-96bd-c90bdb078d02' User entered 'None (0)'	System	18 Nov 2020 22:25:11
	System	18 Nov 2020 22:25:11

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:24:57', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ca05f635-6d01-4d8b-96bd-c90bdb078d02' User entered 'None (0)'	System	18 Nov 2020 22:25:11
	System	18 Nov 2020 22:25:11

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:25:02', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ca05f635-6d01-4d8b-96bd-c90bdb078d02'	System	18 Nov 2020 22:25:11
User entered 'No (N)'	System	18 Nov 2020 22:25:11

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-18T17:25:08', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ca05f635-6d01-4d8b-96bd-c90bdb078d02' User entered '18 Nov 2020 17:25'	System	18 Nov 2020 22:25:11
	System	18 Nov 2020 22:25:11

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '18 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
Data entry locked.	System	13 Nov 2020 17:17:56
User entered 'Day 7'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:34', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '98b63d43-8828-48ed-928f-ce5b1524a0b8' User entered 'None (0)'	System	20 Nov 2020 03:43:00
	System	20 Nov 2020 03:43:00

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:36', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '98b63d43-8828-48ed-928f-ce5b1524a0b8' User entered 'None (0)'	System	20 Nov 2020 03:43:00
	System	20 Nov 2020 03:43:00

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:38', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '98b63d43-8828-48ed-928f-ce5b1524a0b8' User entered 'None (0)'	System	20 Nov 2020 03:43:00
	System	20 Nov 2020 03:43:00

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:40', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '98b63d43-8828-48ed-928f-ce5b1524a0b8' User entered 'None (0)'	System	20 Nov 2020 03:43:00
	System	20 Nov 2020 03:43:00

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:46', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '98b63d43-8828-48ed-928f-ce5b1524a0b8' User entered 'None (0)'	System	20 Nov 2020 03:43:00
	System	20 Nov 2020 03:43:00

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:48', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '98b63d43-8828-48ed-928f-ce5b1524a0b8' User entered 'None (0)'	System	20 Nov 2020 03:43:00
	System	20 Nov 2020 03:43:00

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:51', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '98b63d43-8828-48ed-928f-ce5b1524a0b8' User entered 'No (N)'	System	20 Nov 2020 03:43:00
	System	20 Nov 2020 03:43:00

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CF7F18B-4842-404E-AA42-A9731DAAD182)', Time: '2020-11-19T22:42:54', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '98b63d43-8828-48ed-928f-ce5b1524a0b8' User entered '19 Nov 2020 22:42'	System	20 Nov 2020 03:43:00
	System	20 Nov 2020 03:43:00

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '19 Nov 2020 12:00'	System	13 Nov 2020 17:17:56

US3172374

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:11:23
User entered '20 Nov 2020 11:59'	System	13 Nov 2020 17:17:56

US3172374

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 19:26:17

US3172374

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '23 Nov 2020'	Mariete Rendon (b) (4)	23 Nov 2020 19:26:17
	(b) (4)	

US3172374

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4)	23 Nov 2020 19:26:17
	(b) (4)	

US3172374

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 19:26:17

US3172374

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 19:26:45

US3172374

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'I'	System	23 Nov 2020 19:26:45

US3172374

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Nov 2020 17:32:30

US3172374

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '27 Nov 2020'	Jessie Downs (b) (4) (b) (4)	30 Nov 2020 17:32:30

US3172374

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	30 Nov 2020 17:32:30
	(b) (4)	

US3172374

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Nov 2020 17:32:30

US3172374

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Nov 2020 17:32:35

US3172374

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'I'	System	30 Nov 2020 17:32:35

US3172374

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:56:47

US3172374

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '07 Dec 2020'	Jessie Downs (b) (4)	07 Dec 2020 20:56:47
	(b) (4)	

US3172374

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:56:47

US3172374

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:56:47

US3172374

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	07 Dec 2020 20:56:50

US3172374

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'I'	System	07 Dec 2020 20:56:50

US3172374

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:45:05

US3172374

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '11 Dec 2020'	Jessie Downs (b) (4)	11 Dec 2020 17:45:05
	(b) (4)	

US3172374

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:45:05

US3172374

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'VISIT3'	System	11 Dec 2020 17:45:05

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '11 Dec 2020'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '07:25'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '11 Dec 2020 07:25'	System	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '37.1' C	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '99'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'bpm'	System	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '17'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'breaths/min'	System	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '119'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'mmHg'	System	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '69'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'mmHg'	System	11 Dec 2020 17:47:03

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31

US3172374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31

US3172374

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:48:07

US3172374

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:48:07

US3172374

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:23

US3172374

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '11 Dec 2020'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:23

US3172374

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '08:48'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:47:23

US3172374

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '11 Dec 2020 08:48'	System	11 Dec 2020 17:47:23

US3172374

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 17:45:11

US3172374

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered '1'	System	11 Dec 2020 17:45:11

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-01-21T08:49:44', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '593d51c8-3af7-4776-b16d-5db9994b2b5a' User entered 'No (N)'	System	21 Jan 2021 13:50:26
	System	21 Jan 2021 13:50:26

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-01-21T08:49:48', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '593d51c8-3af7-4776-b16d-5db9994b2b5a' User entered 'No (N)'	System	21 Jan 2021 13:50:26
	System	21 Jan 2021 13:50:26

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-01-21T08:49:55', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '593d51c8-3af7-4776-b16d-5db9994b2b5a' User entered '21 Jan 2021 08:49:55'	System	21 Jan 2021 13:50:26
	System	21 Jan 2021 13:50:26

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-01-26T12:02:13', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '0f91da64-05a3-4d12-97cd-1edfc7b1191d'	System	26 Jan 2021 17:10:46
User entered 'No (N)'	System	26 Jan 2021 17:10:46

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-01-26T12:02:19', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '0f91da64-05a3-4d12-97cd-1edfc7b1191d' User entered 'No (N)'	System	26 Jan 2021 17:10:46

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-01-26T12:02:24', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '0f91da64-05a3-4d12-97cd-1edfc7b1191d' User entered '26 Jan 2021 12:02:24'	System	26 Jan 2021 17:10:46
	System	26 Jan 2021 17:10:46

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-01-31T10:45:21', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4b82f036-fda7-433e-a69a-29171559b407'	System	31 Jan 2021 15:45:31
User entered 'No (N)'	System	31 Jan 2021 15:45:31

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-01-31T10:45:25', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4b82f036-fda7-433e-a69a-29171559b407' User entered 'No (N)'	System	31 Jan 2021 15:45:31

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-01-31T10:45:29', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '4b82f036-fda7-433e-a69a-29171559b407' User entered '31 Jan 2021 10:45:29'	System	31 Jan 2021 15:45:31
	System	31 Jan 2021 15:45:31

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-02-09T19:17:55', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '03d2b860-1c73-4b4c-ab04-b34dc902b9e6'	System	10 Feb 2021 00:20:44
User entered 'No (N)'	System	10 Feb 2021 00:20:44

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-02-09T19:17:58', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '03d2b860-1c73-4b4c-ab04-b34dc902b9e6'	System	10 Feb 2021 00:20:44
User entered 'No (N)'	System	10 Feb 2021 00:20:44

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-02-09T19:18:02', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '03d2b860-1c73-4b4c-ab04-b34dc902b9e6'	System	10 Feb 2021 00:20:44
User entered '09 Feb 2021 19:18:02'	System	10 Feb 2021 00:20:44

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-02-14T00:01:35', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b45865d0-9eab-44ba-9063-8ec11529162b' User entered 'No (N)'	System	14 Feb 2021 05:02:44
	System	14 Feb 2021 05:02:44

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-02-14T00:01:38', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b45865d0-9eab-44ba-9063-8ec11529162b'	System	14 Feb 2021 05:02:44
User entered 'No (N)'	System	14 Feb 2021 05:02:44

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-02-14T00:01:41', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'b45865d0-9eab-44ba-9063-8ec11529162b' User entered '14 Feb 2021 00:01:41'	System	14 Feb 2021 05:02:44
	System	14 Feb 2021 05:02:44

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-02-25T08:46:49', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '24462f5f-901e-4c09-bb61-3e49f50f0049' User entered 'No (N)'	System	25 Feb 2021 13:46:59
	System	25 Feb 2021 13:46:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-02-25T08:46:51', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '24462f5f-901e-4c09-bb61-3e49f50f0049' User entered 'No (N)'	System	25 Feb 2021 13:46:59
	System	25 Feb 2021 13:46:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-02-25T08:46:56', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '24462f5f-901e-4c09-bb61-3e49f50f0049' User entered '25 Feb 2021 08:46:56'	System	25 Feb 2021 13:46:59
	System	25 Feb 2021 13:46:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-02T11:58:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'de86577a-56b6-4dda-83bb-691161a13e61'	System	02 Mar 2021 16:58:13
User entered 'No (N)'	System	02 Mar 2021 16:58:13

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-02T11:58:04', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'de86577a-56b6-4dda-83bb-691161a13e61'	System	02 Mar 2021 16:58:13
User entered 'No (N)'	System	02 Mar 2021 16:58:13

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-02T11:58:08', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'de86577a-56b6-4dda-83bb-691161a13e61'	System	02 Mar 2021 16:58:13
User entered '02 Mar 2021 11:58:08'	System	02 Mar 2021 16:58:13

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-08T14:12:36', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'db6068d7-9782-4ecd-9f36-e0f4b6cbce63'	System	08 Mar 2021 19:12:47
User entered 'No (N)'	System	08 Mar 2021 19:12:47

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-08T14:12:39', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'db6068d7-9782-4ecd-9f36-e0f4b6cbce63'	System	08 Mar 2021 19:12:47
User entered 'No (N)'	System	08 Mar 2021 19:12:47

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-08T14:12:44', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'db6068d7-9782-4ecd-9f36-e0f4b6cbce63' User entered '08 Mar 2021 14:12:44'	System	08 Mar 2021 19:12:47
	System	08 Mar 2021 19:12:47

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-15T10:31:48', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'c343301b-a5f3-4eda-ac36-b51482874c6d' User entered 'No (N)'	System	15 Mar 2021 14:32:03
	System	15 Mar 2021 14:32:03

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-15T10:31:55', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'c343301b-a5f3-4eda-ac36-b51482874c6d' User entered 'No (N)'	System	15 Mar 2021 14:32:03

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-15T10:31:59', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'c343301b-a5f3-4eda-ac36-b51482874c6d' User entered '15 Mar 2021 10:31:59'	System	15 Mar 2021 14:32:03

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-21T19:11:14', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'fcc9773-1620-4955-8423-5396a98a205d' User entered 'No (N)'	System	21 Mar 2021 23:11:22
	System	21 Mar 2021 23:11:22

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-21T19:11:16', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'fcc9773-1620-4955-8423-5396a98a205d' User entered 'No (N)'	System	21 Mar 2021 23:11:22

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-21T19:11:20', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'fcc9773-1620-4955-8423-5396a98a205d' User entered '21 Mar 2021 19:11:20'	System	21 Mar 2021 23:11:22
	System	21 Mar 2021 23:11:22

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-28T00:01:44', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ada42b86-47b6-44bc-8fa1-0aba92d75203'	System	28 Mar 2021 04:02:46
User entered 'No (N)'	System	28 Mar 2021 04:02:46

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-28T00:01:47', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ada42b86-47b6-44bc-8fa1-0aba92d75203'	System	28 Mar 2021 04:02:46
User entered 'No (N)'	System	28 Mar 2021 04:02:46

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-28T00:01:53', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'ada42b86-47b6-44bc-8fa1-0aba92d75203' User entered '28 Mar 2021 00:01:53'	System	28 Mar 2021 04:02:46
	System	28 Mar 2021 04:02:46

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-04T00:01:52-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '70e7ad2d-2821-4c61-9b8f-86f82bd80135' User entered 'No (N)'	System	04 Apr 2021 04:02:59
	System	04 Apr 2021 04:02:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-04T00:01:54-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '70e7ad2d-2821-4c61-9b8f-86f82bd80135' User entered 'No (N)'	System	04 Apr 2021 04:02:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-04T00:01:57-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '70e7ad2d-2821-4c61-9b8f-86f82bd80135'	System	04 Apr 2021 04:02:59
User entered '04 Apr 2021 00:01:57'	System	04 Apr 2021 04:02:59

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-13T12:28:49-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3f5ed2ed-f6a7-4a3d-a871-2d6b7f5eb56f' User entered 'No (N)'	System	13 Apr 2021 16:29:01

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-13T12:28:51-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3f5ed2ed-f6a7-4a3d-a871-2d6b7f5eb56f' User entered 'No (N)'	System	13 Apr 2021 16:29:01

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-13T12:28:54-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '3f5ed2ed-f6a7-4a3d-a871-2d6b7f5eb56f' User entered '13 Apr 2021 12:28:54'	System	13 Apr 2021 16:29:01
	System	13 Apr 2021 16:29:01

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-18T00:12:41-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd767454d-c8db-4a0c-9f11-645b149a076a' User entered 'No (N)'	System	18 Apr 2021 04:12:54
	System	18 Apr 2021 04:12:54

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-18T00:12:45-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd767454d-c8db-4a0c-9f11-645b149a076a' User entered 'No (N)'	System	18 Apr 2021 04:12:54
	System	18 Apr 2021 04:12:54

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-18T00:12:49-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'd767454d-c8db-4a0c-9f11-645b149a076a' User entered '18 Apr 2021 00:12:49'	System	18 Apr 2021 04:12:54
	System	18 Apr 2021 04:12:54

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-25T00:04:58-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '865e4183-e45c-45a6-b00a-ceb02fe721fb' User entered 'No (N)'	System	25 Apr 2021 04:06:07

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-25T00:05:01-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '865e4183-e45c-45a6-b00a-ceb02fe721fb' User entered 'No (N)'	System	25 Apr 2021 04:06:07

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-04-25T00:05:04-04:00', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: '865e4183-e45c-45a6-b00a-ceb02fe721fb' User entered '25 Apr 2021 00:05:04'	System	25 Apr 2021 04:06:07
	System	25 Apr 2021 04:06:07

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 12:52:50

US3172374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:52:50
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 12:52:50

US3172374

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:30:31

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:57:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-02T11:58:15', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e6f2ae19-16cb-4d84-a93d-ff957f0dd09f' User entered 'No (N)'	System	02 Mar 2021 16:58:27
	System	02 Mar 2021 16:58:27

US3172374

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:30:31

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:57:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9317E7F5-8E10-4AF9-B0A2-0BE4AFE17756)', Time: '2021-03-02T11:58:24', User OID: 'PatientReportedOutcome (US3172374)', ODM File OID: 'e6f2ae19-16cb-4d84-a93d-ff957f0dd09f' User entered '02 Mar 2021 11:58:24'	System	02 Mar 2021 16:58:27
	System	02 Mar 2021 16:58:27

US3172374

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:26:12

US3172374

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 05:20:05
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date confirmed as entered. ' (Site from System).	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:26:32
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Jan 2021 22:26:12
User entered '15 Jan 2021'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:26:12

US3172374

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:26:12

US3172374

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:26:12

US3172374

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:26:01

US3172374

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:30:31
User entered 'I'	System	18 Jan 2021 22:26:01

US3172374

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:04:00

US3172374

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:04:00

US3172374

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:04:00

US3172374

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'missed open label'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:04:00

US3172374

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:04:04

US3172374

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:46
User entered 'I'	System	26 Feb 2021 20:04:04

US3172374

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	31 Mar 2021 14:56:29

US3172374

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered empty.	Mariete Rendon (b) (4) (b) (4)	31 Mar 2021 14:56:29

US3172374

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered empty.	Mariete Rendon (b) (4) (b) (4)	31 Mar 2021 14:56:29

US3172374

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:33:58
	(b) (4)	
User entered 'missed, subject in open label.' reason for change: Data Entry Error	Jessie Downs (b) (4)	31 Mar 2021 15:46:11
	(b) (4)	
User entered 'Subject on decision visit'	Mariete Rendon (b) (4)	31 Mar 2021 14:56:29
	(b) (4)	

US3172374

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	31 Mar 2021 14:56:34

US3172374

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 14:56:34

US3172374

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	16 Apr 2021 12:55:16

US3172374

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '15 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 12:55:16

US3172374

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Apr 2021 12:55:16

US3172374

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 12:55:16

US3172374

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	16 Apr 2021 12:55:21

US3172374

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 12:55:21

US3172374

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:42:40

US3172374

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '28 Apr 2021'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:42:40

US3172374

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:42:40

US3172374

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	28 Apr 2021 16:42:40

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '28 Apr 2021'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '07:14'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021 07:14'	System	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '36.7' C	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '80'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '13'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '109'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '69'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Apr 2021 16:43:18

US3172374

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:31

US3172374

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '28 Apr 2021'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:31

US3172374

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:50

US3172374

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '28 Apr 2021'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:50

US3172374

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '07:44'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:50

US3172374

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021 07:44'	System	28 Apr 2021 16:43:50

US3172374

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:43:55

US3172374

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 16:43:55

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:30:31

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '05 Feb 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:00

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:30:31

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '13:07'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:00

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:30:31

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User entered '05 Feb 2021 13:07'	System	05 Feb 2021 20:14:00

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:30:31

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:00

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:30:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:00

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Day 1 (Day 1)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '04 Feb 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User entered empty.	System	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:30:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:18:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Day 2 (Day 2)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '05 Feb 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '98'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User entered '%'	System	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '37.0' C	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Mild (Mild)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Mild (Mild)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Mild (Mild)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Mild (Mild)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:30:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:19:21

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Day 3 (Day 3)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '06 Feb 2021'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '100'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User entered '%'	System	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '97.6' F	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:30:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 18:24:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Day 4 (Day 4)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	08 Feb 2021 22:26:34
User entered '07 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:34
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	08 Feb 2021 22:26:17
User entered '07 Dec 2021'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '99'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User entered '%'	System	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User closed query 'Per CDM: Per sponsor review, please confirm unit of temperature.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:03:20
Query 'Per CDM: Per sponsor review, please confirm unit of temperature.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:47:39
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:47:07
User entered '96.7' F reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:47:07
User opened query 'Per CDM: Per sponsor review, please confirm unit of temperature.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 21:12:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '96.7' C	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:30:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:26:17

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Day 5 (Day 5)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '08 Feb 2021'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '97'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User entered '%'	System	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '97.3' F	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:30:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 22:27:28

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Day 6 (Day 6)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '09 Feb 2021'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '0'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User entered '%'	System	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:30:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Not Done (Not Done)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:06:12

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:30:31

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '05 Feb 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:20

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:30:31

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:20

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:30:31

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:20

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:30:31

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '05 Feb 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:20

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:30:31

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:20

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:30:31

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:20

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:30:31

[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)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:20

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:30:31

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:20

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:30:31

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:20

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:30:31

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User entered '0'	System	05 Feb 2021 20:14:20

US3172374

Folder: Covid-19 Assessment 05 Feb 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:30:31

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:14:09
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:14:25

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:30:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:30:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:30:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:30:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:30:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:30:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:30:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:30:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:30:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:30:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:30:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:30:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:30:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:30:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:30:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:30:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:30:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:30:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:30:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:30:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:30:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:18:15

US3172374

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:16:01

US3172374

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '05 Feb 2021'	Jessie Downs (b) (4)	05 Feb 2021 20:16:01
	(b) (4)	

US3172374

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4)	05 Feb 2021 20:16:01
	(b) (4)	

US3172374

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User entered 'SICKD1'	System	05 Feb 2021 20:16:01

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '05 Feb 2021'	Jessie Downs (b) (4)	05 Feb 2021 20:17:16
	(b) (4)	

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '13:07'	Jessie Downs (b) (4)	05 Feb 2021 20:17:16
	(b) (4)	

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User entered '05 Feb 2021 13:07'	System	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '171.6' cm	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:17:16
DataPoint set to visible.	System	05 Feb 2021 20:16:01

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '069.9' kg	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:17:16
DataPoint set to visible.	System	05 Feb 2021 20:16:01

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '37.0' C	Jessie Downs (b) (4)	05 Feb 2021 20:17:16
	(b) (4)	

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Feb 2021 20:17:16
	(b) (4)	

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '72'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User entered 'bpm'	System	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User entered 'breaths/min'	System	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '127'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User entered 'mmHg'	System	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '61'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User entered 'mmHg'	System	05 Feb 2021 20:17:16

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56

US3172374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56

US3172374

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Feb 2021 20:16:16
	(b) (4)	

US3172374

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '05 Feb 2021'	Jessie Downs (b) (4)	05 Feb 2021 20:16:16
	(b) (4)	

US3172374

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:30:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 20:16:27

US3172374

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:30:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:56
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '05 Feb 2021'	Jessie Downs (b) (4)	05 Feb 2021 20:16:27
	(b) (4)	

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:00:16

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:00:16

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:00:16

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	03 Mar 2021 19:00:16

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 19:02:01

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:05

US3172374

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:05

US3172374

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:30:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:10

US3172374

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:30:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Mar 2021 19:02:10

US3172374

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

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:34:57

US3172374

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

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '26 Jan 2021'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:34:57

US3172374

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

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:34:57

US3172374

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

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 16:34:57

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '06 Jan 2021'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:10

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 17:10:38
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:32:40

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:10

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	(b) (4), (b) (6)	16 Apr 2021 13:48:40
' (Site from DM). Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 17:10:53
' answered with 'Data was updated.' (Site from DM). User entered 'Amendment 6 or later (Amendment 6 or later)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 17:10:38
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	(b) (4), (b) (6)	09 Apr 2021 22:09:29
' (Site from DM). Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:32:40

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '26 Jan 2021'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:10

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:10

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:10

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:10

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:10

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '1'	System	02 Feb 2021 16:36:10

US3172374

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'I'	System	02 Feb 2021 16:36:10

US3172374

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered empty.	System	02 Feb 2021 16:38:05
DataPoint set to visible.	System	02 Feb 2021 16:36:10

US3172374

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered empty.	System	02 Feb 2021 16:38:05
DataPoint set to visible.	System	02 Feb 2021 16:36:10

US3172374

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '26 Jan 2021'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '11:59'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '26 Jan 2021 11:59'	System	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '72'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'bpm'	System	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '16'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'breaths/min'	System	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '122'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mmHg'	System	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '61'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mmHg'	System	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered empty.	System	02 Feb 2021 16:38:05
DataPoint set to visible.	System	02 Feb 2021 16:36:10

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '26 Jan 2021'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '15:24'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '26 Jan 2021 15:24'	System	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '67'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'bpm'	System	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '14'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'breaths/min'	System	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '117'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mmHg'	System	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '66'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mmHg'	System	02 Feb 2021 16:38:05

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:27

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '26 Jan 2021'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:27

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:47

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:47

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	02 Feb 2021 16:36:47
	(b) (4)	

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mRNA-1273'	System	02 Feb 2021 16:36:47
DataPoint set to visible.	System	02 Feb 2021 16:36:10

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '26 Jan 2021'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:47

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '14:54'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:47

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '26 Jan 2021 14:54'	System	02 Feb 2021 16:36:47

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:47

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'ONCE'	System	02 Feb 2021 16:36:47

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 16:36:47

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:35:18

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '26 Jan 2021'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:35:18

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '12:57'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:35:18

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '26 Jan 2021 12:57'	System	02 Feb 2021 16:35:18

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:35:33

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:30:31

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '26 Jan 2021'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:35:33

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:30:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered '12:59'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:35:33

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:30:31

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '26 Jan 2021 12:59'	System	02 Feb 2021 16:35:33

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Feb 2021 16:36:15

US3172374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'I'	System	02 Feb 2021 16:36:15

US3172374

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:29:55

US3172374

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:37
	(b) (4)	
User entered '02 Feb 2021'	Jessie Downs (b) (4)	03 Feb 2021 20:29:55
	(b) (4)	

US3172374

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:29:55

US3172374

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:29:55

US3172374

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:30:00

US3172374

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'I'	System	03 Feb 2021 20:30:00

US3172374

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'I'	System	03 Feb 2021 20:30:00
DataPoint set to visible.	System	03 Feb 2021 20:30:00

US3172374

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:05

US3172374

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '26 Feb 2021'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:05

US3172374

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:05

US3172374

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'OLD29'	System	26 Feb 2021 20:00:05

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '26 Feb 2021'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '09:30'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '26 Feb 2021 09:30'	System	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '36.7' C	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '97'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'bpm'	System	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '17'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'breaths/min'	System	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '127'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mmHg'	System	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '70'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mmHg'	System	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '26 Feb 2021'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '11:48'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '26 Feb 2021 11:48'	System	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '36.6' C	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '94'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'bpm'	System	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '16'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'breaths/min'	System	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '136'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mmHg'	System	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '75'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mmHg'	System	26 Feb 2021 20:01:48

US3172374

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:39

US3172374

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '26 Feb 2021'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:39

US3172374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:24

US3172374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:24

US3172374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:24

US3172374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mRNA-1273'	System	26 Feb 2021 20:00:24
DataPoint set to visible.	System	03 Feb 2021 20:30:00

US3172374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '26 Feb 2021'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:24

US3172374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered '11:18'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:24

US3172374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '26 Feb 2021 11:18'	System	26 Feb 2021 20:00:24

US3172374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:24

US3172374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'ONCE'	System	26 Feb 2021 20:00:24

US3172374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 20:00:24

US3172374

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:00:30

US3172374

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'I'	System	26 Feb 2021 20:00:30

US3172374

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Mar 2021 13:57:10

US3172374

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:43:50
	(b) (4)	
User entered '08 Mar 2021'	Jessie Downs (b) (4)	09 Mar 2021 13:57:10
	(b) (4)	

US3172374

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	09 Mar 2021 13:57:10

US3172374

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Mar 2021 13:57:10

US3172374

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:43:50
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Mar 2021 13:57:18

US3172374

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'I'	System	09 Mar 2021 13:57:18

US3172374

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 12:54:41

US3172374

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '26 Mar 2021'	(b) (4), (b) (6)	09 Apr 2021 12:54:41

US3172374

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Apr 2021 12:54:41

US3172374

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'OLD57'	System	09 Apr 2021 12:54:41

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '26 Mar 2021'	(b) (4), (b) (6)	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '07:41'	(b) (4), (b) (6)	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '26 Mar 2021 07:41'	System	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '36.9' C	(b) (4), (b) (6)	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '83'	(b) (4), (b) (6)	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'bpm'	System	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '18'	(b) (4), (b) (6)	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'breaths/min'	System	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '114'	(b) (4), (b) (6)	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mmHg'	System	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '69'	(b) (4), (b) (6)	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered 'mmHg'	System	09 Apr 2021 12:58:06

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51

US3172374

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:31

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51

US3172374

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 12:58:16

US3172374

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 12:58:16

US3172374

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 12:59:24

US3172374

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '26 Mar 2021'	(b) (4), (b) (6)	09 Apr 2021 12:59:24

US3172374

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:33:58
User entered '08:06'	(b) (4), (b) (6)	09 Apr 2021 12:59:24

US3172374

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:51
User entered '26 Mar 2021 08:06'	System	09 Apr 2021 12:59:24

US3172374

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:30:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:44
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	03 Feb 2021 20:30:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	16 Oct 2020 16:09:55
	(b) (4)	

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 18:55:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 18:55:50
Data point term sent to Coder	System	03 Feb 2021 20:32:59
User entered 'upper respiratory infection - uri'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '31 Jan 2021'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	03 Feb 2021 20:34:10
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	03 Feb 2021 20:34:10
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	03 Feb 2021 20:32:25
User entered '09:00'	Jessie Downs (b) (4)	03 Feb 2021 20:32:25
	(b) (4)	

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User entered empty.	System	03 Feb 2021 20:34:10
User entered '31 Jan 2021 09:00'	System	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:03:12
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:03:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:03:12
User entered '08 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:03:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User entered empty.	System	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 17:31:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 17:31:23
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: New Information	(b) (4), (b) (6)	05 Feb 2021 17:31:23
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 20:32:25
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'I'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:01:21
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:03:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:03:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User entered '0'	System	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10
User entered '0'	System	03 Feb 2021 20:32:25

US3172374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:34:10

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:14
User entered 'USA-US118-2021-mRNA-1273-P301000018'	System	28 Apr 2021 15:45:04
User entered 'New'	(b) (4), (b) (6)	28 Apr 2021 15:45:04

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Skin injuries and mechanical dermatoses, PT: Decubitus ulcer, LLT: Pressure ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 15:55:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 15:55:09
	(b) (4)	
Data point term sent to Coder	System	28 Apr 2021 15:00:19
User entered 'left feet second toe pressure ulcer stage iii'	Jessie Downs (b) (4)	28 Apr 2021 14:59:58
	(b) (4)	

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 16:37:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 16:37:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 16:37:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 14:59:58
User entered empty.	Jessie Downs (b) (4)	28 Apr 2021 14:59:58
	(b) (4)	

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '19 Apr 2021'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Apr 2021 16:37:48
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Apr 2021 14:59:58
User entered 'Yes (Y)'	Jessie Downs (b) (4)	28 Apr 2021 14:59:58
	(b) (4)	

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:37:48
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '19 Apr 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:37:48
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '22 Apr 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:37:48
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Apr 2021 16:37:48
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	28 Apr 2021 14:59:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

None

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '1'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'During the visit Day 209 subject reported an hospitalization period from 19Apr2021 until 22Apr2021 at University of Miami Hospital due to left feet second toe pressure ulcer. The event is still ongoing. PCP and feet care MD are taking care of subject for follow up. We will request records from the hospital.' reason for change: Data Entry Error User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:37:48
	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 14:59:58

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 16:37:48

US3172374

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 16:37:48

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:30:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:00:33

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:21:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:21:07
Data point term sent to Coder	System	23 Nov 2020 19:26:18
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 19:25:38
User entered 'SYMBICORT 1 puff' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 19:25:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:02:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:02:36
Data point term sent to Coder	System	16 Oct 2020 16:01:42
User entered 'SYMBICORT'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than the number of puffs. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:21:00
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than the number of puffs. Please verify the dose and unit, and update as appropriate. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4)	23 Nov 2020 19:25:44
	(b) (4)	
User entered '160/4.5' reason for change: Data Entry Error	Mariete Rendon (b) (4)	23 Nov 2020 19:25:38
	(b) (4)	
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than the number of puffs. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 03:12:12
User entered '1'	Mariete Rendon (b) (4)	16 Oct 2020 16:01:36
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	23 Nov 2020 19:25:38
	(b) (4)	
User entered 'puff (PUFF)'	Mariete Rendon (b) (4)	16 Oct 2020 16:01:36
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'as needed (PRN)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'UN UNK 2000'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:01:36

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:04:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:04:01
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 16:02:43
User entered 'LISINOPRIL'	Mariete Rendon (b) (4)	16 Oct 2020 16:02:03
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'HYPERTENSION'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '20'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'UN UNK 1999'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 16:02:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:04:37
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	16 Oct 2020 16:04:37
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	16 Oct 2020 16:03:43
User entered 'SIMVASTATIN'	Mariete Rendon (b) (4)	16 Oct 2020 16:03:17
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'HYPERLIPIDEMIA'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '40'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'other (OTHER)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'AT NIGHT'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'UN UNK 1999'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:03:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:05:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:05:29
Data point term sent to Coder	System	16 Oct 2020 16:04:44
User entered 'OMEPRAZOLE'	Mariete Rendon (b) (4)	16 Oct 2020 16:04:05
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'ACID RELUX'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '40'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'UN UNK 1990'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 16:04:05

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:40:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:40:23
Data point term sent to Coder Coding entries removed.	System Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 21:39:21 22 Oct 2020 21:38:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:06:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:06:28
Data point term sent to Coder User entered 'HUMALOG'	System Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:46 16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'DIABETES TYPE 1' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Oct 2020 21:38:45
	(b) (4)	
User entered 'DIABETES TYPE 2'	Mariete Rendon (b) (4)	16 Oct 2020 16:05:17
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '60'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'IU (IU)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'UN UNK 2016'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 16:05:17

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 11:56:30
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 11:56:30
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 16:07:48
User entered 'GABAPENTIN'	Mariete Rendon (b) (4)	16 Oct 2020 16:07:03
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'DIABETIC POLYNUEROPATHY'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '300'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'UN UNK 1999'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 16:07:03

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 07:07:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 07:07:48
	(b) (4)	
Data point term sent to Coder	System	20 Nov 2020 20:00:59
Coding entries removed.	Jessie Downs (b) (4)	20 Nov 2020 19:59:58
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:08:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:08:31
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 16:07:49
User entered 'OXYCODONE'	Mariete Rendon (b) (4)	16 Oct 2020 16:07:46
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:24:51
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	20 Nov 2020 20:00:13
	(b) (4)	
User entered 'CHRONIC HIP PAIN' reason for change: Data Entry Error	Jessie Downs (b) (4)	20 Nov 2020 19:59:58
	(b) (4)	
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 03:15:55
User entered 'CHRONIC PAIN'	Mariete Rendon (b) (4)	16 Oct 2020 16:07:46
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '30'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'UN UNK 2000'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 16:07:46

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: BREXPIPRAZOLE, PRODUCTSYNONYM: REXULTI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 09:56:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 09:56:01
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 16:08:51
User entered 'RIXULTI'	Mariete Rendon (b) (4)	16 Oct 2020 16:08:23
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'ANXIETY'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0.50'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 16:08:23

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 21:40:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 21:40:23
	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 21:39:22
Coding entries removed.	Mariete Rendon (b) (4)	22 Oct 2020 21:39:11
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:10:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:10:24
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 16:09:51
User entered 'SEROQUEL'	Mariete Rendon (b) (4)	16 Oct 2020 16:09:08
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'Bip[olar/ DEPRESSION/ insomnia'	Mariete Rendon (b) (4)	22 Oct 2020 21:39:11
reason for change: Data Entry Error	(b) (4)	
User entered 'DEPRESSION'	Mariete Rendon (b) (4)	16 Oct 2020 16:09:08
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '300'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'UN UNK 2000'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 16:09:08

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:33:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 13:56:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 13:56:51
Data point term sent to Coder	System	13 Apr 2021 13:36:13
User closed query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	13 Apr 2021 13:35:52
Query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'Data was updated.' (Site from System).	Jessie Downs (b) (4)	13 Apr 2021 13:35:52
Coding entries removed.	Jessie Downs (b) (4)	13 Apr 2021 13:35:32
Signature has been broken.	Jessie Downs (b) (4)	13 Apr 2021 13:35:32
User entered 'NYQUIL - (Acetaminophen 650mg, Dextromethorphan 30mg, Doxylamine 12.5 mg)' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Apr 2021 13:35:32
User opened query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	06 Apr 2021 15:00:59

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 20:37:29
	(b) (4)	
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 20:37:29
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 20:37:05
User entered 'nyquil'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'upper respiratory infection - uri'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered '15'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'mL (mL)'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered '02 Feb 2021'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	08 Feb 2021 22:27:58
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered '04 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	08 Feb 2021 22:27:58
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:37:28
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	03 Feb 2021 20:36:30
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User entered '1'	System	03 Feb 2021 20:36:30

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User entered '1'	System	03 Feb 2021 20:36:30

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:45:37
User entered '804 (804)'	System	03 Feb 2021 20:36:30

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: MUPIROCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 17:43:13
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 17:43:13
	(b) (4)	
Data point term sent to Coder	System	28 Apr 2021 16:39:50
User entered 'mupirocin'	Jessie Downs (b) (4)	28 Apr 2021 16:39:43
	(b) (4)	

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'left foot 2nd toe pressure ulcer stage iii'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '2'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Other (OTHER)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '%'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Topical (TOPICAL)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '19 Apr 2021'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered '0'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Apr 2021 16:39:43

US3172374

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:30:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:37:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Oct 2020 23:38:56

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:33
User entered		
'USA-US118-2021-MRNA-1273-P301000018'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 16:56:05
Un-reviewed for Safety.	System	28 Apr 2021 16:37:48
User entered 'Yes (Y)'	System	28 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 16:56:05
Un-reviewed for Safety.	System	28 Apr 2021 16:37:48
User entered 'Yes (Y)'	System	28 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'Mark'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'Kutner'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'FL'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 16:56:05
User entered 'US'	System	28 Apr 2021 15:45:44

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Apr 2021 16:56:19
User entered '1'	System	28 Apr 2021 15:45:44

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:33
User entered		
'USA-US118-2021-MRNA-1273-P301000018'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 16:56:05
Un-reviewed for Safety.	System	28 Apr 2021 16:37:48
User entered 'Yes (Y)'	System	28 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 16:56:05
Un-reviewed for Safety.	System	28 Apr 2021 16:37:48
User entered 'Yes (Y)'	System	28 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'Mark'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'Kutner'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'FL'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 16:56:05
User entered 'US'	System	28 Apr 2021 15:45:44

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Apr 2021 16:56:19
User entered '1'	System	28 Apr 2021 15:45:44

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:30:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
User entered '28/Apr/2021 11:45'	System	28 Apr 2021 15:45:44

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:30:31

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.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 16:56:05
User entered 'I'	(b) (4), (b) (6)	28 Apr 2021 15:45:44

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:33
User entered		
'USA-US118-2021-MRNA-1273-P301000018'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 16:56:05
Un-reviewed for Safety.	System	28 Apr 2021 16:37:48
User entered 'Yes (Y)'	System	28 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 16:56:05
Un-reviewed for Safety.	System	28 Apr 2021 16:37:48
User entered 'Yes (Y)'	System	28 Apr 2021 16:37:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'No (N)'	System	28 Apr 2021 15:45:04

US3172374

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'Mark'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'Kutner'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

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[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 15:45:37
User entered 'FL'	System	28 Apr 2021 15:45:04

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 16:56:05
User entered 'US'	System	28 Apr 2021 15:45:44

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Apr 2021 16:56:19
User entered '1'	System	28 Apr 2021 15:45:44

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:30:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 22:26:19
	(b) (4)	
User entered '28/Apr/2021 12:56'	System	28 Apr 2021 16:56:19

US3172374

Folder: SAE USA-US118-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:30:31

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.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:19
User entered 'I'	(b) (4), (b) (6)	28 Apr 2021 16:56:19