

US3172322 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:35:42

All time stamps listed in this document are displayed in GMT

US3172322

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Participant ID

US3172322

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

US3172322

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 25 AUG 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input 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 13:29:37

Generated On: 09 Jun 2021 15:35:42

Date of Informed Consent (<i>dd MMM yyyy</i>)	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input 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 13:29:37

Generated On: 09 Jun 2021 15:35:42

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 13:29:37

Generated On: 09 Jun 2021 15:35:42

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	UMBILICAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	DEGENERATIVE DISC DISEASE
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	TUBAL LIGATION BILATERAL
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	UMBILICAL HERNIA SURGERY
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	LUMBAR SURGERY
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	CHRONIC HEADACHE
Start date (dd MMM yyyy)	17 APR 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)	APR 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	RIGHT SHOULDER CALCIFIC TENDON PAIN
Start date (dd MMM yyyy)	07 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	GENERALIZED OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	LUMBAR RADICULOPATHY
Start date (dd MMM yyyy)	29 APR 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	CHRONIC LEFT SIDED SCIATICA
Start date (dd MMM yyyy)	29 APR 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Condition	LEFT HIP ABSCESS
Start date (dd MMM yyyy)	07 MAR 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)	20 MAR 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAR 2020
Stop Year (derived)	2020

US3172322

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 12:17
Height (xxx.x)	154.0 cm
Weight (xxx.x)	99.0 kg
BMI (xxx.x)	41.74397 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)	

US3172322

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

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: Childbearing Potential

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Date of assessment (dd MMM yyyy) 25 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2002

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:29:37

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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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

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

Visit date (dd MMM yyyy)	25 AUG 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	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:29:48

Generated On: 09 Jun 2021 15:35:42

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 144896

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 13:29:49

Generated On: 09 Jun 2021 15:35:42

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 13:29:49

Generated On: 09 Jun 2021 15:35:42

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)	25 AUG 2020
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 12:17
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 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 13:29:49

Generated On: 09 Jun 2021 15:35:42

Height	ND - Not Done
Weight	ND - Not Done
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)	25 AUG 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:53
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 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 13:29:48

Generated On: 09 Jun 2021 15:35:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 15:20 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 15:20

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 13:29:48

Generated On: 09 Jun 2021 15:35:42

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

Collection date (dd MMM yyyy)	25 AUG 2020
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Collection time (00:00-23:59)	14:03 (24 HR)
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Collection date and time (derived)	25 AUG 2020 14:03
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US3172322

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:01	25 AUG 2020 14:01
Nasopharyngeal Swab 2	No		

US3172322

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

98.6 °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 25 AUG 2020 15:57

PC Open Date & Time 25 AUG 2020 15:40

PC Close Date & Time 25 AUG 2020 18:10

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp	26 AUG 2020 01:04
PC Open Date & Time	25 AUG 2020 19:05
PC Close Date & Time	26 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

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

98.2 °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

26 AUG 2020 12:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

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

97.9 °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

27 AUG 2020 12:17

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 ☒

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 28 AUG 2020 23:02

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 21:59

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:12

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:29

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

25 AUG 2020 15:58

PC Open Date & Time

25 AUG 2020 15:40

PC Close Date & Time

25 AUG 2020 18:10

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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

26 AUG 2020 01:04

PC Open Date & Time

25 AUG 2020 19:05

PC Close Date & Time

26 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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

26 AUG 2020 12:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

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

27 AUG 2020 12:18

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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

28 AUG 2020 23:03

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

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

29 AUG 2020 21:59

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 6
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	30 AUG 2020 12:12
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

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

31 AUG 2020 12:30

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 15:59
PC Open Date & Time	25 AUG 2020 15:40
PC Close Date & Time	25 AUG 2020 18:10

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 01:05
PC Open Date & Time	25 AUG 2020 19:05
PC Close Date & Time	26 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 ☒

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:03
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:19
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 ☒

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 23:03
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 22:00
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

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)

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:13
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:30
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3172322

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

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

Visit date (dd MMM yyyy)	24 SEP 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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US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

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)	24 SEP 2020
Time of assessment (00:00-23:59)	10:59 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:59
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)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

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)	24 SEP 2020
Time of assessment (00:00-23:59)	12:28 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 12:28
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

US3172322

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 11:58 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 11:58

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

What was the frequency of the study treatment dosing? ONCE

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

US3172322

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 24 SEP 2020

Collection time (00:00-23:59) 11:38 (24 HR)

Collection date and time (derived) 24 SEP 2020 11:38

US3172322

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:40	24 SEP 2020 11:40
Nasopharyngeal Swab 2	No		

US3172322

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

98.2 °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

24 SEP 2020 12:30

PC Open Date & Time

24 SEP 2020 12:18

PC Close Date & Time

24 SEP 2020 14:48

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	24 SEP 2020 15:43
PC Open Date & Time	24 SEP 2020 15:43
PC Close Date & Time	25 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

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

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

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

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 100.9 °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):

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

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

PC Time Stamp 27 SEP 2020 10:33

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 100.2 °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):

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

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

PC Time Stamp 27 SEP 2020 21:59

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	100.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	28 SEP 2020 17:50
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

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 ☒

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

29 SEP 2020 20:14

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

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 ☒

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 SEP 2020 19:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

24 SEP 2020 12:30

PC Open Date & Time

24 SEP 2020 12:18

PC Close Date & Time

24 SEP 2020 14:48

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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

24 SEP 2020 15:44

PC Open Date & Time

24 SEP 2020 15:43

PC Close Date & Time

25 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 ☐

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

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

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)**

100

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)**

100

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

27 SEP 2020 10:35

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 ☐

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

2

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)**

200

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

27 SEP 2020 22:01

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

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 ☐

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

200

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)**

200

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

28 SEP 2020 17:51

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

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

200

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

29 SEP 2020 20:15

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

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

30 SEP 2020 19:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 12:31
PC Open Date & Time	24 SEP 2020 12:18
PC Close Date & Time	24 SEP 2020 14:48

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 15:44
PC Open Date & Time	24 SEP 2020 15:43
PC Close Date & Time	25 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

Yes ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

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 ☒

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 10:36
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 22:02
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

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)

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 17:52
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

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 ☒

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 20:16
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

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

120 of 2377

EAB) (1725)

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 19:02
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 9

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3172322

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

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 VISIT3

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

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) _____

US3172322

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

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.

US3172322

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3172322

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:49

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 13:48:24

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 15:13:54
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 17:46:46
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

19 DEC 2020 04:07:31

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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	24 DEC 2020 15:46:37
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

11 JAN 2021 12:46:08

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 JAN 2021 04:54:50
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 14:11:37

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 20:57:50

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 22:39:09

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 00:40:01

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 00:21:26

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 02:05:28

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	05 JUL 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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°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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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°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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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°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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 <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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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="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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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="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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	28 JUL 2022 00:01
Patient Cloud Close Date & Time	01 AUG 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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°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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	22 SEP 2022 00:01
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Patient Cloud Close Date & Time	26 SEP 2022 23:59
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US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3172322

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:35:42

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		23 MAR 2021 13:08:39

US3172322

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 JAN 2021

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

Comments
UNABLE TO CONTACT
SUBJECT. NO VOICEMAIL SET
UP.
If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:29:37

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 FEB 2021

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

Comments
UNABLE TO CONTACT
SUBJECT. PHONE IS NOT IN
SERVICE.

If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:26:04

Generated On: 09 Jun 2021 15:35:42

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 VISIT4

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:26:04

Generated On: 09 Jun 2021 15:35:42

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) _____

US3172322

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:26:04

Generated On: 09 Jun 2021 15:35:42

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.

US3172322

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:26:04

Generated On: 09 Jun 2021 15:35:42

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3172322

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172322

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172322

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Date of Contact	29 SEP 2020
Time of Contact	12:00
Date and Time of Contact (derived)	29 SEP 2020 12:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input 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"/>

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2377

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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 type="radio"/>
	Mild	<input checked="" 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"/>

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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"/>

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

Date	27 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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 type="radio"/>
	Mild	<input checked="" 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"/>

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Symptom Day

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Symptom Day

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

Date	29 SEP 2020
------	-------------

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

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

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

Temperature	36.9 C
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Symptom Day

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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 type="radio"/>
	Mild	<input checked="" 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"/>

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Date of Visit 29 SEP 2020

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

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

Date of Test 29 SEP 2020

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

Other, specify

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

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	29 SEP 2020
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3172322

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

Visit date (dd MMM yyyy)	29 SEP 2020
--------------------------	-------------

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

Folder OID	SICKD1
------------	--------

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	12:07 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 12:07
Height (xxx.x)	154.9 cm
Weight (xxx.x)	097.2 kg
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3172322

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 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 SEP 2020

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

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) _____

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

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.

US3172322

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3172322

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 26 APR 2021

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

Folder OID UNBLND_DECIDE

US3172322

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Date of updated informed consent (dd MMM yyyy)	22 DEC 2020
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 APR 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 type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3172322

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

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

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

Collection time (00:00-23:59)	12:46 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 APR 2021 12:46
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US3172322

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 07:35:01

Generated On: 09 Jun 2021 15:35:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 APR 2021

Collection time (00:00 - 23:59)

12:47

Collection Date and Time (derived)

26 APR 2021 12:47

US3172322

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

AEID

Adverse event

CHRONIC OBSTRUCTIVE
PULMONARY DISEASE ACUTE
EXACERBATION

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)

07 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

10 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

AEID	USA-US118-2020-MRNA-1273-P30 1000004
Adverse event	WORSENING OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 NOV 2020
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)	10 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

SPOKE WITH SUBJECT BY
PHONE FOR DAY 50 SAFETY
CALL. SHE WENT TO THE
EMERGENCY ROOM PER
INVESTIGATOR INSTRUCTIONS
AND WAS ADMITTED ON
10OCT2020. NO INFORMATION
AVAILABLE. STILL IN HOUSE.
WILL REQUEST MEDICAL
RECORDS WHEN DISCHARGED
FOR DETAILS.

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)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

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

Yes ☒

No ☐

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

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HEADACHE/FEVER
Dose per administration	800
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input 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 checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	EVERY 6 HOURS Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HEADACHE/FEVER
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input 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 checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	EVERY 6 HOURS Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

	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)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 NOV 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

Name of Medication	ALBUTEROL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Dose per administration	90
Dose unit	mg <input type="checkbox"/> ug <input checked="" type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	EVERY 6 HOURS Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN UNK 2010
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

Name of Medication	METFORMIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES TYPE II
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

Name of Medication	LISINOPRIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		16 DEC 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

Name of Medication BUDESONIDE FORMOTEROL
(SYMBICORT) 160/4.5 MCG

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

Name of Medication	GABAPENTIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DIABETIC PERIPHERAL NEUROPATHY
Dose per administration	300
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	16 DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

Name of Medication	HYDROCHLOROTHIAZIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	25
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 DEC 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172322

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 13:29:36

Generated On: 09 Jun 2021 15:35:42

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3172322

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:35:42

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

US3172322

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:35:42

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 ☐

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

SAEID	USA-US118-2020-MRNA-1273-P301000004
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)	4

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

SAEID	USA-US118-2020-MRNA-1273-P301000004
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)	4
Date of submission (Pre-filled from custom function)	15/OCT/2020 20:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

SAEID	USA-US118-2020-MRNA-1273-P301000004
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)	4
Date of submission (Pre-filled from custom function)	29/OCT/2020 18:19
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

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

SAEID	USA-US118-2020-MRNA-1273-P301000004
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)	4
Date of submission (Pre-filled from custom function)	25/NOV/2020 13:26
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

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 03 Mar 2021 13:58:50

Generated On: 09 Jun 2021 15:35:42

SAEID	USA-US118-2020-MRNA-1273-P301000004
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)	4
Date of submission (Pre-filled from custom function)	01/MAR/2021 13:11
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

US3172322 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172322

Form: Participant Creation

Generated On: 09 Jun 2021 15:35:42

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'US3172322'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 17:35:09

US3172322

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:07

US3172322

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 17:35:10

US3172322

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:07

US3172322

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'SCRN'	System	25 Aug 2020 20:41:07

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered (b) (6) 1969'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 17:35:11

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '51'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'YEARS'	System	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '51'	System	25 Aug 2020 19:26:21

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Female (F)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:16

US3172322

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:42

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:21

US3172322

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Aug 2020'	System	25 Aug 2020 19:26:21

US3172322

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2020'	System	25 Aug 2020 19:26:21

US3172322

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Amendment 3 (3)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:21

US3172322

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:21

US3172322

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:42

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:21

US3172322

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:21

US3172322

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:21

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 17:35:10

US3172322

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'I'	System	25 Aug 2020 19:26:29

US3172322

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:29

US3172322

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:35:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:55:21

US3172322

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:56:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:56:42
Data point term sent to Coder	System	25 Aug 2020 20:56:17
User entered 'PRESBYOPIA'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:55:40

US3172322

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2018'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:55:40

US3172322

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:55:40

US3172322

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:55:40

US3172322

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:55:40

US3172322

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:55:40

US3172322

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2018'	System	25 Aug 2020 20:55:40

US3172322

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2018'	System	25 Aug 2020 20:55:40

US3172322

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	25 Aug 2020 20:55:40

US3172322

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	25 Aug 2020 20:55:40

US3172322

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:56:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:56:41
Data point term sent to Coder	System	25 Aug 2020 20:56:17
User entered 'TONSILLITIS'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:11

US3172322

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 1977'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:11

US3172322

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:11

US3172322

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:11

US3172322

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 1977'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:11

US3172322

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:11

US3172322

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 1977'	System	25 Aug 2020 20:56:11

US3172322

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '1977'	System	25 Aug 2020 20:56:11

US3172322

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 1977'	System	25 Aug 2020 20:56:11

US3172322

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '1977'	System	25 Aug 2020 20:56:11

US3172322

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:58:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:58:32
Data point term sent to Coder	System	25 Aug 2020 20:57:18
User entered 'UMBILICAL HERNIA'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:38

US3172322

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2002'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:38

US3172322

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:38

US3172322

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:38

US3172322

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2002'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:38

US3172322

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:38

US3172322

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2002'	System	25 Aug 2020 20:56:38

US3172322

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2002'	System	25 Aug 2020 20:56:38

US3172322

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2002'	System	25 Aug 2020 20:56:38

US3172322

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2002'	System	25 Aug 2020 20:56:38

US3172322

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
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)	25 Aug 2020 20:58:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:58:32
Data point term sent to Coder	System	25 Aug 2020 20:57:18
User entered 'OSTEOPOROSIS'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:58

US3172322

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2016'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:58

US3172322

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:58

US3172322

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:58

US3172322

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:58

US3172322

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:56:58

US3172322

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2016'	System	25 Aug 2020 20:56:58

US3172322

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2016'	System	25 Aug 2020 20:56:58

US3172322

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	25 Aug 2020 20:56:58

US3172322

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	25 Aug 2020 20:56:58

US3172322

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:59:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:59:35
Data point term sent to Coder	System	25 Aug 2020 20:58:24
User entered 'DEGENERATIVE DISC DISEASE'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:57:51

US3172322

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2016'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:57:51

US3172322

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:57:51

US3172322

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:57:51

US3172322

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:57:51

US3172322

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:57:51

US3172322

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2016'	System	25 Aug 2020 20:57:51

US3172322

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2016'	System	25 Aug 2020 20:57:51

US3172322

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	25 Aug 2020 20:57:51

US3172322

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	25 Aug 2020 20:57:51

US3172322

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 14:02:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 14:02:17
Data point term sent to Coder	System	12 Oct 2020 14:01:13
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:00:50
User entered 'TUBAL LIGATION Bilateral' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:00:50
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:59:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:59:36
Data point term sent to Coder	System	25 Aug 2020 20:58:25
User entered 'TUBAL LIGATION'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:24

US3172322

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2002'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:24

US3172322

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:24

US3172322

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:24

US3172322

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2002'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:24

US3172322

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:24

US3172322

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2002'	System	25 Aug 2020 20:58:24

US3172322

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2002'	System	25 Aug 2020 20:58:24

US3172322

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2002'	System	25 Aug 2020 20:58:24

US3172322

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2002'	System	25 Aug 2020 20:58:24

US3172322

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:00:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:00:37
Data point term sent to Coder	System	25 Aug 2020 20:59:26
User entered 'TONSILLECTOMY'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:44

US3172322

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 1977'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:44

US3172322

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:44

US3172322

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:44

US3172322

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 1977'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:44

US3172322

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:58:44

US3172322

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 1977'	System	25 Aug 2020 20:58:44

US3172322

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '1977'	System	25 Aug 2020 20:58:44

US3172322

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 1977'	System	25 Aug 2020 20:58:44

US3172322

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '1977'	System	25 Aug 2020 20:58:44

US3172322

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Umbilical hernia repair, LLT: Umbilical hernia repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:00:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:00:37
Data point term sent to Coder	System	25 Aug 2020 20:59:28
User entered 'UMBILICAL HERNIA SURGERY'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:04

US3172322

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2002'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:04

US3172322

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:04

US3172322

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:04

US3172322

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2002'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:04

US3172322

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:04

US3172322

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2002'	System	25 Aug 2020 20:59:04

US3172322

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2002'	System	25 Aug 2020 20:59:04

US3172322

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2002'	System	25 Aug 2020 20:59:04

US3172322

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2002'	System	25 Aug 2020 20:59:04

US3172322

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. '(Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:36:30
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Lumbar surgery due to degenerative disc disease.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	11 Sep 2020 20:38:22
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. '(Site from DM).	(b) (4), (b) (6)	09 Sep 2020 02:28:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:01:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:01:41
Data point term sent to Coder	System	25 Aug 2020 21:00:29
User entered 'LUMBAR SURGERY'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:30

US3172322

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2012'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:30

US3172322

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:30

US3172322

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:30

US3172322

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2012'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:30

US3172322

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:30

US3172322

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2012'	System	25 Aug 2020 20:59:30

US3172322

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2012'	System	25 Aug 2020 20:59:30

US3172322

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2012'	System	25 Aug 2020 20:59:30

US3172322

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2012'	System	25 Aug 2020 20:59:30

US3172322

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User coded data point as SOC: Surgical and medical procedures, HLT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:41:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:41:57
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:36:54
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Sacral surgery due to degenerative disc disease.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	11 Sep 2020 20:39:25
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 03:13:51
Data point term sent to Coder	System	25 Aug 2020 21:00:29
User entered 'SACRAL SURGERY'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:48

US3172322

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2016'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:48

US3172322

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:48

US3172322

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:48

US3172322

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2016'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:48

US3172322

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:59:48

US3172322

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2016'	System	25 Aug 2020 20:59:48

US3172322

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2016'	System	25 Aug 2020 20:59:48

US3172322

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2016'	System	25 Aug 2020 20:59:48

US3172322

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2016'	System	25 Aug 2020 20:59:48

US3172322

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
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)	22 Oct 2020 03:31:38
Query 'Per DM CLR: Please note that there is no Con Mariete Rendon 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 'No Treatment' (Site from DM).	(b) (4) (b) (4)	15 Oct 2020 18:37:09
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)	15 Oct 2020 05:50:41
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:34:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:34:38
Data point term sent to Coder	System	28 Sep 2020 18:33:30
User entered 'hypertension'	Mariete Rendon (b) (4) (b) (4)	28 Sep 2020 18:33:21

US3172322

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:35:01
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 16:47:05
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 16:47:05
User entered 'UN UNK 2015' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 16:47:05
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'un Jan 2020'	Mariete Rendon (b) (4)	28 Sep 2020 18:33:21
	(b) (4)	

US3172322

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	28 Sep 2020 18:33:21

US3172322

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	28 Sep 2020 18:33:21

US3172322

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Sep 2020 18:33:21

US3172322

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Mariete Rendon (b) (4) (b) (4)	28 Sep 2020 18:33:21

US3172322

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2015'	System	23 Apr 2021 16:47:05
User entered 'Jan 2020'	System	28 Sep 2020 18:33:21

US3172322

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2015'	System	23 Apr 2021 16:47:05
User entered '2020'	System	28 Sep 2020 18:33:21

US3172322

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	28 Sep 2020 18:33:21

US3172322

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	28 Sep 2020 18:33:21

US3172322

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:10:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:10:01
Data point term sent to Coder	System	29 Sep 2020 13:09:17
User entered 'SEVERE OBESITY'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:20

US3172322

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2020'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:20

US3172322

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:20

US3172322

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:20

US3172322

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:20

US3172322

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:20

US3172322

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2020'	System	29 Sep 2020 13:08:20

US3172322

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2020'	System	29 Sep 2020 13:08:20

US3172322

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	29 Sep 2020 13:08:20

US3172322

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	29 Sep 2020 13:08:20

US3172322

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:10:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:10:02
Data point term sent to Coder	System	29 Sep 2020 13:09:17
User entered 'CHRONIC BACK PAIN'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:55

US3172322

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'UN UNK 2016'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:55

US3172322

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:55

US3172322

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:55

US3172322

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:55

US3172322

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:08:55

US3172322

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2016'	System	29 Sep 2020 13:08:55

US3172322

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2016'	System	29 Sep 2020 13:08:55

US3172322

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	29 Sep 2020 13:08:55

US3172322

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	29 Sep 2020 13:08:55

US3172322

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
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)	09 Oct 2020 21:53:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:53:29
Data point term sent to Coder	System	09 Oct 2020 21:52:45
User entered 'Mild Chronic Obstructive Pulmonary Disease'	(b) (4), (b) (6)	09 Oct 2020 21:52:18

US3172322

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'un UNK 2010'	(b) (4), (b) (6)	09 Oct 2020 21:52:18

US3172322

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 21:52:18

US3172322

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:52:18

US3172322

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:52:18

US3172322

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:25:23
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 21:52:18

US3172322

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2010'	System	09 Oct 2020 21:52:18

US3172322

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2010'	System	09 Oct 2020 21:52:18

US3172322

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	09 Oct 2020 21:52:18

US3172322

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	09 Oct 2020 21:52:18

US3172322

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 16:59:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 16:59:07
Data point term sent to Coder	System	20 Jan 2021 16:58:46
User entered 'diabetic peripheral neuropathy'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:58:43

US3172322

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'un UNK 2019'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:58:43

US3172322

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:58:43

US3172322

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:58:43

US3172322

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:58:43

US3172322

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:58:43

US3172322

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2019'	System	20 Jan 2021 16:58:43

US3172322

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2019'	System	20 Jan 2021 16:58:43

US3172322

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 16:58:43

US3172322

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 16:58:43

US3172322

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Chronic headaches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 17:02:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 17:02:05
Data point term sent to Coder	System	20 Jan 2021 17:00:47
User entered 'chronic headache'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:59:53

US3172322

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '17 Apr 2010'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:59:53

US3172322

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:59:53

US3172322

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:59:53

US3172322

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:59:53

US3172322

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 16:59:53

US3172322

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Apr 2010'	System	20 Jan 2021 16:59:53

US3172322

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2010'	System	20 Jan 2021 16:59:53

US3172322

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 16:59:53

US3172322

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 16:59:53

US3172322

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:35:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 17:03:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 17:03:07
Data point term sent to Coder	System	20 Jan 2021 17:01:48
User entered 'diabetes type ii'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:01:07

US3172322

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'un UNK 2019'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:01:07

US3172322

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:01:07

US3172322

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:01:07

US3172322

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:01:07

US3172322

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:01:07

US3172322

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:35:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2019'	System	20 Jan 2021 17:01:07

US3172322

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2019'	System	20 Jan 2021 17:01:07

US3172322

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 17:01:07

US3172322

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 17:01:07

US3172322

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:35:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendon pain, LLT: Tendon pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 07:23:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 07:23:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Data point term sent to Coder	System	20 Jan 2021 17:30:12
User entered 'right shoulder calcific tendon pain'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:30:09

US3172322

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '07 Aug 2020'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:30:09

US3172322

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:30:09

US3172322

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:30:09

US3172322

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:30:09

US3172322

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:30:09

US3172322

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Aug 2020'	System	20 Jan 2021 17:30:09

US3172322

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2020'	System	20 Jan 2021 17:30:09

US3172322

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 17:30:09

US3172322

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 17:30:09

US3172322

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 17:33:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 17:33:05
Data point term sent to Coder	System	20 Jan 2021 17:32:13
User entered 'generalized osteoarthritis'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:31:27

US3172322

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'un UNK 2016'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:31:27

US3172322

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:31:27

US3172322

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:31:27

US3172322

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:31:27

US3172322

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:31:27

US3172322

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:35:42

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Jan 2016'	System	20 Jan 2021 17:31:27

US3172322

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2016'	System	20 Jan 2021 17:31:27

US3172322

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 17:31:27

US3172322

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 17:31:27

US3172322

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Lumbar radiculopathy, LLT: Lumbar radiculopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 17:35:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 17:35:05
Data point term sent to Coder	System	20 Jan 2021 17:34:16
User entered 'lumbar radiculopathy'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:33:25

US3172322

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '29 Apr 2016'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:33:25

US3172322

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:33:25

US3172322

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:33:25

US3172322

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:33:25

US3172322

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:33:25

US3172322

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Apr 2016'	System	20 Jan 2021 17:33:25

US3172322

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2016'	System	20 Jan 2021 17:33:25

US3172322

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 17:33:25

US3172322

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 17:33:25

US3172322

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:35:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 22:57:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 22:57:09
Data point term sent to Coder	System	20 Jan 2021 17:34:16
User entered 'chronic left sided sciatica'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:34:16

US3172322

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:35:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User closed query 'Start date is missing and Start date System is completely unknown has not been checked. Please correct.' (Site from System).		20 Jan 2021 17:34:31
User entered '29 Apr 2016' reason for change: Data Entry Error	Jessie Downs (b) (4)	20 Jan 2021 17:34:31
	(b) (4)	
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	20 Jan 2021 17:34:16
User entered empty.	Jessie Downs (b) (4)	20 Jan 2021 17:34:16
	(b) (4)	

US3172322

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:34:16

US3172322

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:34:16

US3172322

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:34:16

US3172322

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:34:16

US3172322

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Apr 2016'	System	20 Jan 2021 17:34:31
User entered empty.	System	20 Jan 2021 17:34:16

US3172322

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2016'	System	20 Jan 2021 17:34:31
User entered empty.	System	20 Jan 2021 17:34:16

US3172322

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 17:34:16

US3172322

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered empty.	System	20 Jan 2021 17:34:16

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:35:01
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User closed query 'Per DM CLR: Please update the condition to include the location of LEFT ABSCESS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	26 Apr 2021 17:35:23
' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Joint abscess, LLT: Joint abscess - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:24:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:24:00
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Joint abscess, LLT: Joint abscess - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:23:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:23:01
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:22:38
User closed query 'CDM-Coding: Please enter the location of ABSCESS in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	System	23 Apr 2021 16:21:47
Query 'CDM-Coding: Please enter the location of ABSCESS in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' answered with 'Data updated ' (Site from System).	(b) (4), (b) (6)	23 Apr 2021 16:21:47
Data point term sent to Coder	System	23 Apr 2021 16:21:37

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the condition to include the location of LEFT ABSCESS. 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).	(b) (4), (b) (6)	23 Apr 2021 16:21:27
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 16:20:59
User entered 'LEFT HIP ABSCESS' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 16:20:59
User opened query 'CDM-Coding: Please enter the location of ABSCESS in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4)	10 Mar 2021 11:39:50
User opened query 'Per DM CLR: Please update the condition to include the location of LEFT ABSCESS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	09 Mar 2021 08:23:27
' (Site from DM).		
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:58:50
	(b) (4)	
Data point term sent to Coder	System	24 Feb 2021 22:04:39
User entered 'left abscess'	Jessie Downs (b) (4)	24 Feb 2021 22:04:01
	(b) (4)	

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered '07 Mar 2020'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 22:04:01

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 22:04:01

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 22:04:01

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered '20 Mar 2020'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 22:04:01

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 22:04:01

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Mar 2020'	System	24 Feb 2021 22:04:01

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2020'	System	24 Feb 2021 22:04:01

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'Mar 2020'	System	24 Feb 2021 22:04:01

US3172322

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '2020'	System	24 Feb 2021 22:04:01

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '12:17'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered '25 Aug 2020 12:17'	System	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '154.0' cm	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55
DataPoint set to visible.	System	25 Aug 2020 19:26:29

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '99.0' kg	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55
DataPoint set to visible.	System	25 Aug 2020 19:26:29

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
Amendment Manager: User entered '41.74397'	System	17 Sep 2020 00:02:10
User entered '41.7'	System	25 Aug 2020 20:42:55
DataPoint set to visible.	System	25 Aug 2020 19:26:29

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'kg/m2'	System	25 Aug 2020 20:42:55
DataPoint set to visible.	System	25 Aug 2020 19:26:29

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'bpm'	System	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'breaths/min'	System	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'mmHg'	System	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User entered 'mmHg'	System	25 Aug 2020 20:42:55

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46

US3172322

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46

US3172322

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:46:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:43:34

US3172322

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	05 Oct 2020 15:46:07
	(b) (4)	
User entered '25 Aug 2020'	Mariete Rendon (b) (4)	25 Aug 2020 20:43:34
	(b) (4)	

US3172322

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:48:52

US3172322

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:42

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:48:52

US3172322

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:42

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 21:08:09
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' answered with 'Data updated in medical history log' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:01:41
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 12:50:16
User entered 'Surgically sterile (SURGICALLY STERILE)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:48:52

US3172322

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:42

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:48:52

US3172322

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:42

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'UN UNK 2002'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:48:52

US3172322

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:42

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:48:52

US3172322

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:48:52

US3172322

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:42

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:48:52

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

[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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

[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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

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)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:41:43

US3172322

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:49:13

US3172322

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:49:13

US3172322

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:49:13

US3172322

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'VISIT1'	System	25 Aug 2020 20:49:13

US3172322

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 17:35:17

US3172322

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:42

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '144896'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 17:35:17

US3172322

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:42

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 17:35:17

US3172322

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:42

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)	04 Apr 2021 11:45:51
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 22:29:05
User closed query 'Per late entry on source, history of COPD since 2010.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:28:45
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:28:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:49
	(b) (4)	
Query 'Per late entry on source, history of COPD since 2010.' answered by data change (Site from CRA).	System	11 Jan 2021 20:13:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	11 Jan 2021 20:13:52
User opened query 'Per late entry on source, history of COPD since 2010.' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 17:24:46
User entered 'No (N)'	Mariete Rendon (b) (4)	25 Aug 2020 21:04:04
	(b) (4)	

US3172322

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:42

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)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:04:04

US3172322

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:42

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:04:04

US3172322

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:42

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:04:04

US3172322

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:04:04

US3172322

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:42

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:44:04
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 07:52:15
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:52:13

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '12:17'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered '25 Aug 2020 12:17'	System	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '36.8' C	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '80'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'bpm'	System	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '14'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'breaths/min'	System	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '131'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'mmHg'	System	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '74'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'mmHg'	System	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 12:09:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 12:09:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 12:09:49
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 20:50:24
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '25 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 12:09:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '15:53' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 12:09:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered '25 Aug 2020 15:53'	System	26 Aug 2020 12:09:49
User entered empty.	System	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '37.0' C reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 12:09:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 12:09:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '56' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 12:09:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'bpm'	System	26 Aug 2020 12:09:49
User entered empty.	System	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '16' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 12:09:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'breaths/min'	System	26 Aug 2020 12:09:49
User entered empty.	System	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '150' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 12:09:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'mmHg'	System	26 Aug 2020 12:09:49
User entered empty.	System	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '86' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 12:09:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'mmHg'	System	26 Aug 2020 12:09:49
User entered empty.	System	25 Aug 2020 20:50:24

US3172322

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:46:26
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:35

US3172322

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '25 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:46:26
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 20:50:35

US3172322

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:59

US3172322

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:59

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

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)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:59

US3172322

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 19:26:59

US3172322

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '25 Aug 2020'	Mariete Rendon (b) (4)	25 Aug 2020 19:26:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '15:20'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:59

US3172322

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered '25 Aug 2020 15:20'	System	25 Aug 2020 19:26:59

US3172322

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 19:26:59

US3172322

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'ONCE'	System	25 Aug 2020 19:26:59

US3172322

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 19:26:59

US3172322

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:04:52

US3172322

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:04:52

US3172322

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '14:03'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:04:52

US3172322

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered '25 Aug 2020 14:03'	System	25 Aug 2020 21:04:52

US3172322

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:35:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:05:06

US3172322

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:05:06

US3172322

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:05:06

US3172322

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '14:01'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:05:06

US3172322

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:42

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered '25 Aug 2020 14:01'	System	25 Aug 2020 21:05:06

US3172322

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:05:06

US3172322

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:23:08
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:05:06

US3172322

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:23:08
User entered '14:01'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:05:06

US3172322

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:42

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered empty.	System	17 Sep 2020 15:23:08
User entered '25 Aug 2020 14:01'	System	25 Aug 2020 21:05:06

US3172322

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 12:09:57

US3172322

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'I'	System	26 Aug 2020 12:09:57

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:56:57', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '438ed3eb-d496-4238-ae1c-ed10b5cea915'	System	25 Aug 2020 19:57:19
User entered 'Yes (Y)'	System	25 Aug 2020 19:57:19

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:57:03', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '438ed3eb-d496-4238-ae1c-ed10b5cea915'	System	25 Aug 2020 19:57:19
User entered '98.6'	System	25 Aug 2020 19:57:19

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:57:07', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '438ed3eb-d496-4238-ae1c-ed10b5cea915'	System	25 Aug 2020 19:57:19
User entered 'No (N)'	System	25 Aug 2020 19:57:19

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:57:15', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '438ed3eb-d496-4238-ae1c-ed10b5cea915'	System	25 Aug 2020 19:57:19
User entered '25 Aug 2020 15:57'	System	25 Aug 2020 19:57:19

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Aug 2020 15:40'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Aug 2020 18:10'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:03:13', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e2549e20-433d-4a66-8c45-e1d4b3130382'	System	26 Aug 2020 05:04:08
User entered 'Yes (Y)'	System	26 Aug 2020 05:04:08

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:03:27', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e2549e20-433d-4a66-8c45-e1d4b3130382'	System	26 Aug 2020 05:04:08
User entered '98.5'	System	26 Aug 2020 05:04:08

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:03:34', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e2549e20-433d-4a66-8c45-e1d4b3130382'	System	26 Aug 2020 05:04:08
User entered 'No (N)'	System	26 Aug 2020 05:04:08

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e2549e20-433d-4a66-8c45-e1d4b3130382'	System	26 Aug 2020 05:04:08
User entered '26 Aug 2020 01:04'	System	26 Aug 2020 05:04:08

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Aug 2020 19:05'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 2'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:01:39', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '624b231e-ee5e-4a45-9f59-b6a9b3739b1a'	System	26 Aug 2020 16:02:47
User entered 'Yes (Y)'	System	26 Aug 2020 16:02:47

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:01:48', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '624b231e-ee5e-4a45-9f59-b6a9b3739b1a' User entered '98.2'	System	26 Aug 2020 16:02:47
	System	26 Aug 2020 16:02:47

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:01:55', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '624b231e-ee5e-4a45-9f59-b6a9b3739b1a'	System	26 Aug 2020 16:02:47
User entered 'No (N)'	System	26 Aug 2020 16:02:47

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:02:13', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '624b231e-ee5e-4a45-9f59-b6a9b3739b1a'	System	26 Aug 2020 16:02:47
User entered '26 Aug 2020 12:02'	System	26 Aug 2020 16:02:47

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 3'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:17:28', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '0653910b-8b50-45f3-a04d-6d4e585f2d43'	System	27 Aug 2020 16:17:57
User entered 'Yes (Y)'	System	27 Aug 2020 16:17:57

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:17:41', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '0653910b-8b50-45f3-a04d-6d4e585f2d43'	System	27 Aug 2020 16:17:57
User entered '97.9'	System	27 Aug 2020 16:17:57

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:17:48', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '0653910b-8b50-45f3-a04d-6d4e585f2d43'	System	27 Aug 2020 16:17:57
User entered 'No (N)'	System	27 Aug 2020 16:17:57

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:17:52', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '0653910b-8b50-45f3-a04d-6d4e585f2d43'	System	27 Aug 2020 16:17:57
User entered '27 Aug 2020 12:17'	System	27 Aug 2020 16:17:57

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 4'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:02:30', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '93b896dc-2a94-4d02-8d16-be430b290235'	System	29 Aug 2020 03:02:46
User entered 'No (N)'	System	29 Aug 2020 03:02:46

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:02:38', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '93b896dc-2a94-4d02-8d16-be430b290235'	System	29 Aug 2020 03:02:46
User entered 'No (N)'	System	29 Aug 2020 03:02:46

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:02:41', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '93b896dc-2a94-4d02-8d16-be430b290235'	System	29 Aug 2020 03:02:46
User entered '28 Aug 2020 23:02'	System	29 Aug 2020 03:02:46

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 5'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:58:56', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1d0d363f-72e6-4518-b530-df95168010f6'	System	30 Aug 2020 01:59:17
User entered 'Yes (Y)'	System	30 Aug 2020 01:59:17

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:04', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1d0d363f-72e6-4518-b530-df95168010f6'	System	30 Aug 2020 01:59:17
User entered '98.2'	System	30 Aug 2020 01:59:17

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:11', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1d0d363f-72e6-4518-b530-df95168010f6'	System	30 Aug 2020 01:59:17
User entered 'No (N)'	System	30 Aug 2020 01:59:17

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:15', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1d0d363f-72e6-4518-b530-df95168010f6'	System	30 Aug 2020 01:59:17
User entered '29 Aug 2020 21:59'	System	30 Aug 2020 01:59:17

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 6'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:11:51', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5a243cba-c266-4efa-a093-1db829a3c5f8'	System	30 Aug 2020 16:12:10
User entered 'Yes (Y)'	System	30 Aug 2020 16:12:10

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5a243cba-c266-4efa-a093-1db829a3c5f8'	System	30 Aug 2020 16:12:10
User entered '98.3'	System	30 Aug 2020 16:12:10

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:05', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5a243cba-c266-4efa-a093-1db829a3c5f8'	System	30 Aug 2020 16:12:10
User entered 'No (N)'	System	30 Aug 2020 16:12:10

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:07', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5a243cba-c266-4efa-a093-1db829a3c5f8'	System	30 Aug 2020 16:12:10
User entered '30 Aug 2020 12:12'	System	30 Aug 2020 16:12:10

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 7'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:29:41', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '98641ab5-6471-427c-b652-c6122cf3c506'	System	31 Aug 2020 16:34:30
User entered 'Yes (Y)'	System	31 Aug 2020 16:34:30

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:29:49', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '98641ab5-6471-427c-b652-c6122cf3c506'	System	31 Aug 2020 16:34:30
User entered '98.2'	System	31 Aug 2020 16:34:30

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:29:53', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '98641ab5-6471-427c-b652-c6122cf3c506'	System	31 Aug 2020 16:34:30
User entered 'No (N)'	System	31 Aug 2020 16:34:30

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:29:56', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '98641ab5-6471-427c-b652-c6122cf3c506'	System	31 Aug 2020 16:34:30
User entered '31 Aug 2020 12:29'	System	31 Aug 2020 16:34:30

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:58:25', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b84ff085-2727-486f-a479-fba2f49c3395'	System	25 Aug 2020 19:58:54
User entered 'None (1)'	System	25 Aug 2020 19:58:54

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:58:33', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b84ff085-2727-486f-a479-fba2f49c3395'	System	25 Aug 2020 19:58:54
User entered 'No (N)'	System	25 Aug 2020 19:58:54

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:58:36', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b84ff085-2727-486f-a479-fba2f49c3395'	System	25 Aug 2020 19:58:54
User entered 'No (N)'	System	25 Aug 2020 19:58:54

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:58:44', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b84ff085-2727-486f-a479-fba2f49c3395'	System	25 Aug 2020 19:58:54
User entered 'None (1)'	System	25 Aug 2020 19:58:54

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:58:50', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b84ff085-2727-486f-a479-fba2f49c3395'	System	25 Aug 2020 19:58:54
User entered '25 Aug 2020 15:58'	System	25 Aug 2020 19:58:54

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Aug 2020 15:40'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Aug 2020 18:10'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:04:13', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '2a68d888-a731-43cd-97a6-cad93790e9df'	System	26 Aug 2020 05:04:44
User entered 'None (1)'	System	26 Aug 2020 05:04:44

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:04:19', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '2a68d888-a731-43cd-97a6-cad93790e9df'	System	26 Aug 2020 05:04:44
User entered 'No (N)'	System	26 Aug 2020 05:04:44

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:04:26', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '2a68d888-a731-43cd-97a6-cad93790e9df'	System	26 Aug 2020 05:04:44
User entered 'No (N)'	System	26 Aug 2020 05:04:44

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:04:34', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '2a68d888-a731-43cd-97a6-cad93790e9df'	System	26 Aug 2020 05:04:44
User entered 'None (1)'	System	26 Aug 2020 05:04:44

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:04:40', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '2a68d888-a731-43cd-97a6-cad93790e9df'	System	26 Aug 2020 05:04:44
User entered '26 Aug 2020 01:04'	System	26 Aug 2020 05:04:44

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Aug 2020 19:05'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 2'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:02:24', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7471fb81-32a4-4213-8239-05ae0cda7c00'	System	26 Aug 2020 16:03:19
User entered 'None (1)'	System	26 Aug 2020 16:03:19

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:02:29', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7471fb81-32a4-4213-8239-05ae0cda7c00'	System	26 Aug 2020 16:03:19
User entered 'No (N)'	System	26 Aug 2020 16:03:19

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:02:36', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7471fb81-32a4-4213-8239-05ae0cda7c00'	System	26 Aug 2020 16:03:19
User entered 'No (N)'	System	26 Aug 2020 16:03:19

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:02:44', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7471fb81-32a4-4213-8239-05ae0cda7c00'	System	26 Aug 2020 16:03:19
User entered 'None (1)'	System	26 Aug 2020 16:03:19

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:02:51', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7471fb81-32a4-4213-8239-05ae0cda7c00'	System	26 Aug 2020 16:03:19
User entered '26 Aug 2020 12:02'	System	26 Aug 2020 16:03:19

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 3'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:17:59', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9ef29cfe-23c2-4136-b535-9cedc46fa2ac'	System	27 Aug 2020 16:18:32
User entered 'None (1)'	System	27 Aug 2020 16:18:32

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:18:06', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9ef29cfe-23c2-4136-b535-9cedc46fa2ac'	System	27 Aug 2020 16:18:32
User entered 'No (N)'	System	27 Aug 2020 16:18:32

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:18:12', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9ef29cfe-23c2-4136-b535-9cedc46fa2ac'	System	27 Aug 2020 16:18:32
User entered 'No (N)'	System	27 Aug 2020 16:18:32

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:18:23', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9ef29cfe-23c2-4136-b535-9cedc46fa2ac'	System	27 Aug 2020 16:18:32
User entered 'None (1)'	System	27 Aug 2020 16:18:32

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:18:28', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9ef29cfe-23c2-4136-b535-9cedc46fa2ac'	System	27 Aug 2020 16:18:32
User entered '27 Aug 2020 12:18'	System	27 Aug 2020 16:18:32

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 4'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:02:49', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '03be1ee7-fb13-4d60-9676-b992201de3a7'	System	29 Aug 2020 03:03:13
User entered 'None (1)'	System	29 Aug 2020 03:03:13

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:02:53', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '03be1ee7-fb13-4d60-9676-b992201de3a7'	System	29 Aug 2020 03:03:13
User entered 'No (N)'	System	29 Aug 2020 03:03:13

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:02:57', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '03be1ee7-fb13-4d60-9676-b992201de3a7'	System	29 Aug 2020 03:03:13
User entered 'No (N)'	System	29 Aug 2020 03:03:13

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:03:03', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '03be1ee7-fb13-4d60-9676-b992201de3a7'	System	29 Aug 2020 03:03:13
User entered 'None (1)'	System	29 Aug 2020 03:03:13

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:03:07', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '03be1ee7-fb13-4d60-9676-b992201de3a7'	System	29 Aug 2020 03:03:13
User entered '28 Aug 2020 23:03'	System	29 Aug 2020 03:03:13

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 5'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:21', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b0877c59-b8a5-481a-8211-0bc7d0064314'	System	30 Aug 2020 01:59:43
User entered 'None (1)'	System	30 Aug 2020 01:59:43

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:26', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b0877c59-b8a5-481a-8211-0bc7d0064314'	System	30 Aug 2020 01:59:43
User entered 'No (N)'	System	30 Aug 2020 01:59:43

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:31', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b0877c59-b8a5-481a-8211-0bc7d0064314'	System	30 Aug 2020 01:59:43
User entered 'No (N)'	System	30 Aug 2020 01:59:43

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:36', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b0877c59-b8a5-481a-8211-0bc7d0064314'	System	30 Aug 2020 01:59:43
User entered 'None (1)'	System	30 Aug 2020 01:59:43

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:41', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b0877c59-b8a5-481a-8211-0bc7d0064314'	System	30 Aug 2020 01:59:43
User entered '29 Aug 2020 21:59'	System	30 Aug 2020 01:59:43

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 6'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:13', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1d81eef8-ad1d-4e98-8039-c93a2cc95961'	System	30 Aug 2020 16:12:35
User entered 'None (1)'	System	30 Aug 2020 16:12:35

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:17', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1d81eef8-ad1d-4e98-8039-c93a2cc95961'	System	30 Aug 2020 16:12:35
User entered 'No (N)'	System	30 Aug 2020 16:12:35

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:21', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1d81eef8-ad1d-4e98-8039-c93a2cc95961'	System	30 Aug 2020 16:12:35
User entered 'No (N)'	System	30 Aug 2020 16:12:35

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:27', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1d81eef8-ad1d-4e98-8039-c93a2cc95961'	System	30 Aug 2020 16:12:35
User entered 'None (1)'	System	30 Aug 2020 16:12:35

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:30', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1d81eef8-ad1d-4e98-8039-c93a2cc95961'	System	30 Aug 2020 16:12:35
User entered '30 Aug 2020 12:12'	System	30 Aug 2020 16:12:35

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 7'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:01', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '4e21ae55-2a20-46ca-bfc4-0665a986add2'	System	31 Aug 2020 16:34:44
User entered 'None (1)'	System	31 Aug 2020 16:34:44

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:06', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '4e21ae55-2a20-46ca-bfc4-0665a986add2'	System	31 Aug 2020 16:34:44
User entered 'No (N)'	System	31 Aug 2020 16:34:44

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:09', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '4e21ae55-2a20-46ca-bfc4-0665a986add2'	System	31 Aug 2020 16:34:44
User entered 'No (N)'	System	31 Aug 2020 16:34:44

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:14', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '4e21ae55-2a20-46ca-bfc4-0665a986add2'	System	31 Aug 2020 16:34:44
User entered 'None (1)'	System	31 Aug 2020 16:34:44

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:17', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '4e21ae55-2a20-46ca-bfc4-0665a986add2'	System	31 Aug 2020 16:34:44
User entered '31 Aug 2020 12:30'	System	31 Aug 2020 16:34:44

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:58:57', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'bed573d5-3b77-4df4-8ad5-239d00b1644c'	System	25 Aug 2020 19:59:34
User entered 'None (0)'	System	25 Aug 2020 19:59:34

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:58:59', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'bed573d5-3b77-4df4-8ad5-239d00b1644c'	System	25 Aug 2020 19:59:34
User entered 'None (0)'	System	25 Aug 2020 19:59:34

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:59:04', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'bed573d5-3b77-4df4-8ad5-239d00b1644c'	System	25 Aug 2020 19:59:34
User entered 'None (0)'	System	25 Aug 2020 19:59:34

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:59:10', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'bed573d5-3b77-4df4-8ad5-239d00b1644c'	System	25 Aug 2020 19:59:34
User entered 'None (0)'	System	25 Aug 2020 19:59:34

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:59:12', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'bed573d5-3b77-4df4-8ad5-239d00b1644c'	System	25 Aug 2020 19:59:34
User entered 'None (0)'	System	25 Aug 2020 19:59:34

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:59:14', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'bed573d5-3b77-4df4-8ad5-239d00b1644c'	System	25 Aug 2020 19:59:34
User entered 'None (0)'	System	25 Aug 2020 19:59:34

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:59:25', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'bed573d5-3b77-4df4-8ad5-239d00b1644c'	System	25 Aug 2020 19:59:34
User entered 'No (N)'	System	25 Aug 2020 19:59:34

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-25T15:59:29', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'bed573d5-3b77-4df4-8ad5-239d00b1644c'	System	25 Aug 2020 19:59:34
User entered '25 Aug 2020 15:59'	System	25 Aug 2020 19:59:34

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Aug 2020 15:40'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Aug 2020 18:10'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:04:47', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '41359c94-e736-4b19-9e64-858bbfe40a2c'	System	26 Aug 2020 05:05:35
User entered 'None (0)'	System	26 Aug 2020 05:05:35

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:04:54', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '41359c94-e736-4b19-9e64-858bbfe40a2c'	System	26 Aug 2020 05:05:35
User entered 'None (0)'	System	26 Aug 2020 05:05:35

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:04:59', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '41359c94-e736-4b19-9e64-858bbfe40a2c'	System	26 Aug 2020 05:05:35
User entered 'None (0)'	System	26 Aug 2020 05:05:35

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:05:04', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '41359c94-e736-4b19-9e64-858bbfe40a2c'	System	26 Aug 2020 05:05:35
User entered 'None (0)'	System	26 Aug 2020 05:05:35

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:05:08', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '41359c94-e736-4b19-9e64-858bbfe40a2c'	System	26 Aug 2020 05:05:35
User entered 'None (0)'	System	26 Aug 2020 05:05:35

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:05:12', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '41359c94-e736-4b19-9e64-858bbfe40a2c'	System	26 Aug 2020 05:05:35
User entered 'None (0)'	System	26 Aug 2020 05:05:35

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:05:27', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '41359c94-e736-4b19-9e64-858bbfe40a2c'	System	26 Aug 2020 05:05:35
User entered 'No (N)'	System	26 Aug 2020 05:05:35

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T01:05:31', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '41359c94-e736-4b19-9e64-858bbfe40a2c'	System	26 Aug 2020 05:05:35
User entered '26 Aug 2020 01:05'	System	26 Aug 2020 05:05:35

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Aug 2020 19:05'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 2'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:03:03', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '432739f1-3ff1-41eb-9c8f-0b26cd091247'	System	26 Aug 2020 16:03:55
User entered 'None (0)'	System	26 Aug 2020 16:03:55

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:03:10', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '432739f1-3ff1-41eb-9c8f-0b26cd091247'	System	26 Aug 2020 16:03:55
User entered 'None (0)'	System	26 Aug 2020 16:03:55

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:03:18', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '432739f1-3ff1-41eb-9c8f-0b26cd091247'	System	26 Aug 2020 16:03:55
User entered 'None (0)'	System	26 Aug 2020 16:03:55

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:03:23', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '432739f1-3ff1-41eb-9c8f-0b26cd091247'	System	26 Aug 2020 16:03:55
User entered 'None (0)'	System	26 Aug 2020 16:03:55

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:03:28', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '432739f1-3ff1-41eb-9c8f-0b26cd091247'	System	26 Aug 2020 16:03:55
User entered 'None (0)'	System	26 Aug 2020 16:03:55

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:03:33', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '432739f1-3ff1-41eb-9c8f-0b26cd091247'	System	26 Aug 2020 16:03:55
User entered 'None (0)'	System	26 Aug 2020 16:03:55

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:03:42', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '432739f1-3ff1-41eb-9c8f-0b26cd091247'	System	26 Aug 2020 16:03:55
User entered 'No (N)'	System	26 Aug 2020 16:03:55

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-26T12:03:47', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '432739f1-3ff1-41eb-9c8f-0b26cd091247'	System	26 Aug 2020 16:03:55
User entered '26 Aug 2020 12:03'	System	26 Aug 2020 16:03:55

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 3'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:18:39', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fcd9ab13-15f8-41e8-a303-66d4f8c238f1' User entered 'None (0)'	System	27 Aug 2020 16:19:19
	System	27 Aug 2020 16:19:19

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:18:43', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fcd9ab13-15f8-41e8-a303-66d4f8c238f1'	System	27 Aug 2020 16:19:19
User entered 'None (0)'	System	27 Aug 2020 16:19:19

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:18:48', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fcd9ab13-15f8-41e8-a303-66d4f8c238f1'	System	27 Aug 2020 16:19:19
User entered 'None (0)'	System	27 Aug 2020 16:19:19

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:18:56', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fcd9ab13-15f8-41e8-a303-66d4f8c238f1'	System	27 Aug 2020 16:19:19
User entered 'None (0)'	System	27 Aug 2020 16:19:19

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:19:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fcd9ab13-15f8-41e8-a303-66d4f8c238f1' User entered 'None (0)'	System	27 Aug 2020 16:19:19
	System	27 Aug 2020 16:19:19

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:19:04', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fcd9ab13-15f8-41e8-a303-66d4f8c238f1'	System	27 Aug 2020 16:19:19
User entered 'None (0)'	System	27 Aug 2020 16:19:19

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:19:10', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fcd9ab13-15f8-41e8-a303-66d4f8c238f1'	System	27 Aug 2020 16:19:19
User entered 'No (N)'	System	27 Aug 2020 16:19:19

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-27T12:19:13', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fcd9ab13-15f8-41e8-a303-66d4f8c238f1'	System	27 Aug 2020 16:19:19
User entered '27 Aug 2020 12:19'	System	27 Aug 2020 16:19:19

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 4'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:03:12', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '320cb23f-08aa-46cf-ba37-b6fff5ad2c17'	System	29 Aug 2020 03:03:52
User entered 'None (0)'	System	29 Aug 2020 03:03:52

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:03:20', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '320cb23f-08aa-46cf-ba37-b6fff5ad2c17'	System	29 Aug 2020 03:03:52
User entered 'None (0)'	System	29 Aug 2020 03:03:52

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:03:26', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '320cb23f-08aa-46cf-ba37-b6fff5ad2c17'	System	29 Aug 2020 03:03:52
User entered 'None (0)'	System	29 Aug 2020 03:03:52

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:03:32', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '320cb23f-08aa-46cf-ba37-b6fff5ad2c17'	System	29 Aug 2020 03:03:52
User entered 'None (0)'	System	29 Aug 2020 03:03:52

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:03:37', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '320cb23f-08aa-46cf-ba37-b6fff5ad2c17'	System	29 Aug 2020 03:03:52
User entered 'None (0)'	System	29 Aug 2020 03:03:52

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:03:40', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '320cb23f-08aa-46cf-ba37-b6fff5ad2c17'	System	29 Aug 2020 03:03:52
User entered 'None (0)'	System	29 Aug 2020 03:03:52

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:03:45', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '320cb23f-08aa-46cf-ba37-b6fff5ad2c17'	System	29 Aug 2020 03:03:52
User entered 'No (N)'	System	29 Aug 2020 03:03:52

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-28T23:03:48', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '320cb23f-08aa-46cf-ba37-b6fff5ad2c17'	System	29 Aug 2020 03:03:52
User entered '28 Aug 2020 23:03'	System	29 Aug 2020 03:03:52

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 5'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:48', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '625edef1-49e4-4459-b2f4-2602fd4e7209'	System	30 Aug 2020 02:00:29
User entered 'None (0)'	System	30 Aug 2020 02:00:29

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:51', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '625edef1-49e4-4459-b2f4-2602fd4e7209'	System	30 Aug 2020 02:00:29
User entered 'None (0)'	System	30 Aug 2020 02:00:29

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:54', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '625edef1-49e4-4459-b2f4-2602fd4e7209'	System	30 Aug 2020 02:00:29
User entered 'None (0)'	System	30 Aug 2020 02:00:29

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T21:59:59', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '625edef1-49e4-4459-b2f4-2602fd4e7209'	System	30 Aug 2020 02:00:29
User entered 'None (0)'	System	30 Aug 2020 02:00:29

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T22:00:03', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '625edef1-49e4-4459-b2f4-2602fd4e7209'	System	30 Aug 2020 02:00:29
User entered 'None (0)'	System	30 Aug 2020 02:00:29

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T22:00:07', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '625edef1-49e4-4459-b2f4-2602fd4e7209'	System	30 Aug 2020 02:00:29
User entered 'None (0)'	System	30 Aug 2020 02:00:29

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T22:00:21', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '625edef1-49e4-4459-b2f4-2602fd4e7209'	System	30 Aug 2020 02:00:29
User entered 'No (N)'	System	30 Aug 2020 02:00:29

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-29T22:00:24', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '625edef1-49e4-4459-b2f4-2602fd4e7209'	System	30 Aug 2020 02:00:29
User entered '29 Aug 2020 22:00'	System	30 Aug 2020 02:00:29

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 6'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:37', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fdec5067-bf76-4132-ab96-62cb4fcc0df5'	System	30 Aug 2020 16:13:13
User entered 'None (0)'	System	30 Aug 2020 16:13:13

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:40', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fdec5067-bf76-4132-ab96-62cb4fcc0df5'	System	30 Aug 2020 16:13:13
User entered 'None (0)'	System	30 Aug 2020 16:13:13

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:45', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fdec5067-bf76-4132-ab96-62cb4fcc0df5'	System	30 Aug 2020 16:13:13
User entered 'None (0)'	System	30 Aug 2020 16:13:13

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:50', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fdec5067-bf76-4132-ab96-62cb4fcc0df5'	System	30 Aug 2020 16:13:13
User entered 'None (0)'	System	30 Aug 2020 16:13:13

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:54', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fdec5067-bf76-4132-ab96-62cb4fcc0df5'	System	30 Aug 2020 16:13:13
User entered 'None (0)'	System	30 Aug 2020 16:13:13

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:12:58', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fdec5067-bf76-4132-ab96-62cb4fcc0df5'	System	30 Aug 2020 16:13:13
User entered 'None (0)'	System	30 Aug 2020 16:13:13

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:13:04', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fdec5067-bf76-4132-ab96-62cb4fcc0df5'	System	30 Aug 2020 16:13:13
User entered 'No (N)'	System	30 Aug 2020 16:13:13

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-30T12:13:08', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fdec5067-bf76-4132-ab96-62cb4fcc0df5'	System	30 Aug 2020 16:13:13
User entered '30 Aug 2020 12:13'	System	30 Aug 2020 16:13:13

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 7'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:23', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '25a3d218-3dd6-4c84-bbfa-786f2bc22031'	System	31 Aug 2020 16:34:56
User entered 'None (0)'	System	31 Aug 2020 16:34:56

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:27', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '25a3d218-3dd6-4c84-bbfa-786f2bc22031'	System	31 Aug 2020 16:34:56
User entered 'None (0)'	System	31 Aug 2020 16:34:56

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:30', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '25a3d218-3dd6-4c84-bbfa-786f2bc22031' User entered 'None (0)'	System	31 Aug 2020 16:34:56
	System	31 Aug 2020 16:34:56

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:34', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '25a3d218-3dd6-4c84-bbfa-786f2bc22031'	System	31 Aug 2020 16:34:56
User entered 'None (0)'	System	31 Aug 2020 16:34:56

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:37', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '25a3d218-3dd6-4c84-bbfa-786f2bc22031'	System	31 Aug 2020 16:34:56
User entered 'None (0)'	System	31 Aug 2020 16:34:56

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:40', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '25a3d218-3dd6-4c84-bbfa-786f2bc22031'	System	31 Aug 2020 16:34:56
User entered 'None (0)'	System	31 Aug 2020 16:34:56

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:48', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '25a3d218-3dd6-4c84-bbfa-786f2bc22031'	System	31 Aug 2020 16:34:56
User entered 'No (N)'	System	31 Aug 2020 16:34:56

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-08-31T12:30:51', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '25a3d218-3dd6-4c84-bbfa-786f2bc22031'	System	31 Aug 2020 16:34:56
User entered '31 Aug 2020 12:30'	System	31 Aug 2020 16:34:56

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:26:59

US3172322

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Sep 2020 21:00:09

US3172322

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '02 Sep 2020'	Jessie Downs (b) (4) (b) (4)	02 Sep 2020 21:00:09

US3172322

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	02 Sep 2020 21:00:09

US3172322

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Sep 2020 21:00:09

US3172322

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Sep 2020 21:00:16

US3172322

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User entered 'I'	System	02 Sep 2020 21:00:16

US3172322

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 14:19:34

US3172322

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '9 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 14:19:34

US3172322

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 14:19:34

US3172322

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 14:19:34

US3172322

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 14:19:39

US3172322

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User entered 'I'	System	14 Sep 2020 14:19:39

US3172322

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:00:37

US3172322

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '15 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:00:37

US3172322

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:00:37

US3172322

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:00:37

US3172322

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:36:28

US3172322

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User entered 'I'	System	17 Sep 2020 15:36:28

US3172322

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User closed query 'Per GCL Lab Recon: GCL is reporting receiving a SARS sample dated 29Sep2020, however, no COVID-19 Assessment Contact, Symptom Log, Diagnostic test, or Illness visit has been completed matching this date. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 03:39:36
Query 'Per GCL Lab Recon: GCL is reporting receiving a SARS sample dated 29Sep2020, however, no COVID-19 Assessment Contact, Symptom Log, Diagnostic test, or Illness visit has been completed matching this date. Please reconcile.' answered with 'Data was entered.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:59:33
User opened query 'Per GCL Lab Recon: GCL is reporting receiving a SARS sample dated 29Sep2020, however, no COVID-19 Assessment Contact, Symptom Log, Diagnostic test, or Illness visit has been completed matching this date. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 23:02:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:09:15

US3172322

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:09:15

US3172322

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:09:15

US3172322

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'VISIT2'	System	24 Sep 2020 16:09:15

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '10:59'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered '24 Sep 2020 10:59'	System	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '36.6' C	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '99'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'bpm'	System	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '16'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'breaths/min'	System	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '141'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'mmHg'	System	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '81'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'mmHg'	System	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '12:28'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered '24 Sep 2020 12:28'	System	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '88'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'bpm'	System	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '16'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'breaths/min'	System	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '166'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'mmHg'	System	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '98'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'mmHg'	System	25 Sep 2020 15:51:56

US3172322

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:49:03

US3172322

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Sep 2020 15:49:10
User entered '24 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:49:10
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Sep 2020 15:49:03
User entered '25 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:49:03

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:08:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 16:24:05
Query 'Data is required. Please complete.' answered with 'DATA ENTERED IN ERROR' (Site from System).	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 16:04:56
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 16:04:46
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 16:04:46
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:36:47

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:36:47

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

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)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:36:47

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 16:08:55
User entered empty.	System	17 Sep 2020 16:04:46
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 15:36:47

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '24 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:08:55
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 16:04:46
User entered '17 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:36:47

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '11:58' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:08:55
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 16:04:46
User entered '11:31'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:36:47

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered '24 Sep 2020 11:58'	System	24 Sep 2020 16:08:55
User entered empty.	System	17 Sep 2020 16:04:46
User entered '17 Sep 2020 11:31'	System	17 Sep 2020 15:36:47

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:08:55
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 16:04:46
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:36:47

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'ONCE'	System	24 Sep 2020 16:08:55
User entered empty.	System	17 Sep 2020 16:04:46
User entered 'ONCE'	System	17 Sep 2020 15:36:47

US3172322

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 16:08:55
User entered empty.	System	17 Sep 2020 16:04:46
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 15:36:47

US3172322

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:49:31

US3172322

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:49:31

US3172322

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '11:38'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:49:31

US3172322

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered '24 Sep 2020 11:38'	System	25 Sep 2020 15:49:31

US3172322

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:35:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:50:00

US3172322

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:50:00

US3172322

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:50:00

US3172322

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered '11:40'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:50:00

US3172322

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered '24 Sep 2020 11:40'	System	25 Sep 2020 15:50:00

US3172322

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User closed query 'Were 2 NP swabs done on visit 2? If only 1 please leave swab 2 section blank' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:16:43
Comment added 'Data was updated. 2 swab not done.'	Jessie Downs (b) (4)	07 Oct 2020 15:50:24
Query 'Were 2 NP swabs done on visit 2? If only 1 please leave swab 2 section blank' answered with 'Data was updated' (Site from CRA).	Jessie Downs (b) (4)	02 Oct 2020 14:34:51
User opened query 'Were 2 NP swabs done on visit 2? If only 1 please leave swab 2 section blank' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 17:32:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessie Downs (b) (4)	25 Sep 2020 15:50:00

US3172322

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 14:34:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:50:00

US3172322

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 14:34:41
User entered '11:40'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:50:00

US3172322

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:42

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered empty.	System	02 Oct 2020 14:34:41
User entered '24 Sep 2020 11:40'	System	25 Sep 2020 15:50:00

US3172322

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:50:08

US3172322

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'I'	System	25 Sep 2020 15:50:08

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:30:13', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '6575eaf4-5f3a-45e1-bbff-35219a4be606'	System	24 Sep 2020 16:30:31
User entered 'Yes (Y)'	System	24 Sep 2020 16:30:31

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:30:19', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '6575eaf4-5f3a-45e1-bbff-35219a4be606'	System	24 Sep 2020 16:30:31
User entered '98.2'	System	24 Sep 2020 16:30:31

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:30:23', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '6575eaf4-5f3a-45e1-bbff-35219a4be606'	System	24 Sep 2020 16:30:31
User entered 'No (N)'	System	24 Sep 2020 16:30:31

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:30:28', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '6575eaf4-5f3a-45e1-bbff-35219a4be606'	System	24 Sep 2020 16:30:31
User entered '24 Sep 2020 12:30'	System	24 Sep 2020 16:30:31

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '24 Sep 2020 12:18'	System	24 Sep 2020 16:08:55
User entered '17 Sep 2020 11:51'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '24 Sep 2020 14:48'	System	24 Sep 2020 16:08:55
User entered '17 Sep 2020 14:21'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:43:30', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '79b6f4f0-1ef0-4068-8e40-73846d3be533'	System	24 Sep 2020 19:43:50
User entered 'Yes (Y)'	System	24 Sep 2020 19:43:50

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:43:36', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '79b6f4f0-1ef0-4068-8e40-73846d3be533'	System	24 Sep 2020 19:43:50
User entered '98.2'	System	24 Sep 2020 19:43:50

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:43:40', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '79b6f4f0-1ef0-4068-8e40-73846d3be533'	System	24 Sep 2020 19:43:50
User entered 'No (N)'	System	24 Sep 2020 19:43:50

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:43:46', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '79b6f4f0-1ef0-4068-8e40-73846d3be533'	System	24 Sep 2020 19:43:50
User entered '24 Sep 2020 15:43'	System	24 Sep 2020 19:43:50

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '24 Sep 2020 15:43'	System	24 Sep 2020 16:08:55
User entered '17 Sep 2020 15:16'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 2'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 3'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:32:24', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a6582d24-a6a9-490d-8f86-503ccdc07444'	System	27 Sep 2020 14:33:26
User entered 'Yes (Y)'	System	27 Sep 2020 14:33:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:32:56', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a6582d24-a6a9-490d-8f86-503ccdc07444'	System	27 Sep 2020 14:33:26
User entered '100.9'	System	27 Sep 2020 14:33:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:33:03', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a6582d24-a6a9-490d-8f86-503ccdc07444'	System	27 Sep 2020 14:33:26
User entered 'Yes (Y)'	System	27 Sep 2020 14:33:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Con med page was updated ' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 19:06:14
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Jessie Downs (b) (4)	29 Sep 2020 13:09:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:33:16', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a6582d24-a6a9-490d-8f86-503ccdc07444'	(b) (4)	
User entered '1'	System	27 Sep 2020 14:33:26
	System	27 Sep 2020 14:33:26
	System	27 Sep 2020 14:33:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:33:16', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a6582d24-a6a9-490d-8f86-503ccdc07444'	System	27 Sep 2020 14:33:26
User entered '0'	System	27 Sep 2020 14:33:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:33:22', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a6582d24-a6a9-490d-8f86-503ccdc07444'	System	27 Sep 2020 14:33:26
User entered '27 Sep 2020 10:33'	System	27 Sep 2020 14:33:26

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 4'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T21:59:23', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a42d3484-4a2f-4cc1-86dd-4631bc8aeded'	System	28 Sep 2020 01:59:54
User entered 'Yes (Y)'	System	28 Sep 2020 01:59:54

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T21:59:31', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a42d3484-4a2f-4cc1-86dd-4631bc8aeded' User entered '100.2'	System	28 Sep 2020 01:59:54
	System	28 Sep 2020 01:59:54

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T21:59:37', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a42d3484-4a2f-4cc1-86dd-4631bc8aeded'	System	28 Sep 2020 01:59:54
User entered 'Yes (Y)'	System	28 Sep 2020 01:59:54

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Con med page was updated ' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 19:06:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Jessie Downs (b) (4)	29 Sep 2020 13:10:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T21:59:44', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a42d3484-4a2f-4cc1-86dd-4631bc8aeded'	(b) (4)	
User entered '1'	System	28 Sep 2020 01:59:54
	System	28 Sep 2020 01:59:54
	System	28 Sep 2020 01:59:54

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T21:59:44', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a42d3484-4a2f-4cc1-86dd-4631bc8aeded' User entered '0'	System	28 Sep 2020 01:59:54
	System	28 Sep 2020 01:59:54

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T21:59:51', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a42d3484-4a2f-4cc1-86dd-4631bc8aeded'	System	28 Sep 2020 01:59:54
User entered '27 Sep 2020 21:59'	System	28 Sep 2020 01:59:54

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 5'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:49:54', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '42eabf35-7660-45d3-ae26-a40311c78d78'	System	28 Sep 2020 21:50:48
User entered 'Yes (Y)'	System	28 Sep 2020 21:50:48

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:50:15', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '42eabf35-7660-45d3-ae26-a40311c78d78'	System	28 Sep 2020 21:50:48
User entered '100.2'	System	28 Sep 2020 21:50:48

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:50:20', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '42eabf35-7660-45d3-ae26-a40311c78d78'	System	28 Sep 2020 21:50:48
User entered 'Yes (Y)'	System	28 Sep 2020 21:50:48

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Con med page was updated ' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 19:06:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Con med page was updated ' (Site from System).	Jessie Downs (b) (4)	29 Sep 2020 13:10:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	28 Sep 2020 21:50:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:50:29', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '42eabf35-7660-45d3-ae26-a40311c78d78'	System	28 Sep 2020 21:50:48
User entered '1'	System	28 Sep 2020 21:50:48

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:50:29', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '42eabf35-7660-45d3-ae26-a40311c78d78'	System	28 Sep 2020 21:50:48
User entered '0'	System	28 Sep 2020 21:50:48

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:50:32', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '42eabf35-7660-45d3-ae26-a40311c78d78'	System	28 Sep 2020 21:50:48
User entered '28 Sep 2020 17:50'	System	28 Sep 2020 21:50:48

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 6'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:14:20', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '99845b06-a582-4cdb-a9cf-0eb06497f2b1'	System	30 Sep 2020 00:14:46
User entered 'No (N)'	System	30 Sep 2020 00:14:46

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:14:29', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '99845b06-a582-4cdb-a9cf-0eb06497f2b1'	System	30 Sep 2020 00:14:46
User entered 'Yes (Y)'	System	30 Sep 2020 00:14:46

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:14:39', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '99845b06-a582-4cdb-a9cf-0eb06497f2b1'	System	30 Sep 2020 00:14:46
User entered '0'	System	30 Sep 2020 00:14:46

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject is in convalescent period. ' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 19:06:33
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Jessie Downs (b) (4)	30 Sep 2020 16:08:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:14:39', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '99845b06-a582-4cdb-a9cf-0eb06497f2b1'	(b) (4)	
User entered '1'	System	30 Sep 2020 00:14:46
	System	30 Sep 2020 00:14:46
	System	30 Sep 2020 00:14:46

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:14:43', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '99845b06-a582-4cdb-a9cf-0eb06497f2b1'	System	30 Sep 2020 00:14:46
User entered '29 Sep 2020 20:14'	System	30 Sep 2020 00:14:46

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 7'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:01:43', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '2e4225f7-e6c2-4985-a967-77a04a6d3279'	System	30 Sep 2020 23:02:01
User entered 'No (N)'	System	30 Sep 2020 23:02:01

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:01:50', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '2e4225f7-e6c2-4985-a967-77a04a6d3279'	System	30 Sep 2020 23:02:01
User entered 'Yes (Y)'	System	30 Sep 2020 23:02:01

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'See conmed log' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 19:06:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:01:56', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '2e4225f7-e6c2-4985-a967-77a04a6d3279'	Mariete Rendon (b) (4)	05 Oct 2020 16:15:05
User entered '1'	System	30 Sep 2020 23:02:01
	System	30 Sep 2020 23:02:01
	System	30 Sep 2020 23:02:01

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:01:56', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '2e4225f7-e6c2-4985-a967-77a04a6d3279'	System	30 Sep 2020 23:02:01
User entered '0'	System	30 Sep 2020 23:02:01

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:01:59', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '2e4225f7-e6c2-4985-a967-77a04a6d3279'	System	30 Sep 2020 23:02:01
User entered '30 Sep 2020 19:01'	System	30 Sep 2020 23:02:01

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:30:38', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '6461780e-c50a-4e28-9905-b6cbb99b6c89'	System	24 Sep 2020 16:30:58
User entered 'None (1)'	System	24 Sep 2020 16:30:58

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:30:43', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '6461780e-c50a-4e28-9905-b6cbb99b6c89'	System	24 Sep 2020 16:30:58
User entered 'No (N)'	System	24 Sep 2020 16:30:58

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:30:47', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '6461780e-c50a-4e28-9905-b6cbb99b6c89'	System	24 Sep 2020 16:30:58
User entered 'No (N)'	System	24 Sep 2020 16:30:58

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:30:53', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '6461780e-c50a-4e28-9905-b6cbb99b6c89'	System	24 Sep 2020 16:30:58
User entered 'None (1)'	System	24 Sep 2020 16:30:58

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:30:55', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '6461780e-c50a-4e28-9905-b6cbb99b6c89'	System	24 Sep 2020 16:30:58
User entered '24 Sep 2020 12:30'	System	24 Sep 2020 16:30:58

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '24 Sep 2020 12:18'	System	24 Sep 2020 16:08:55
User entered '17 Sep 2020 11:51'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '24 Sep 2020 14:48'	System	24 Sep 2020 16:08:55
User entered '17 Sep 2020 14:21'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:43:52', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '545eca86-d1b3-4e2f-ad07-89731d1e7826'	System	24 Sep 2020 19:44:19
User entered 'None (1)'	System	24 Sep 2020 19:44:19

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:43:57', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '545eca86-d1b3-4e2f-ad07-89731d1e7826'	System	24 Sep 2020 19:44:19
User entered 'No (N)'	System	24 Sep 2020 19:44:19

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:03', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '545eca86-d1b3-4e2f-ad07-89731d1e7826'	System	24 Sep 2020 19:44:19
User entered 'No (N)'	System	24 Sep 2020 19:44:19

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:09', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '545eca86-d1b3-4e2f-ad07-89731d1e7826'	System	24 Sep 2020 19:44:19
User entered 'None (1)'	System	24 Sep 2020 19:44:19

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:16', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '545eca86-d1b3-4e2f-ad07-89731d1e7826'	System	24 Sep 2020 19:44:19
User entered '24 Sep 2020 15:44'	System	24 Sep 2020 19:44:19

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '24 Sep 2020 15:43'	System	24 Sep 2020 16:08:55
User entered '17 Sep 2020 15:16'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 2'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 3'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:33:49', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9da118e2-87ea-4e45-ac1b-d92a24dc0b31'	System	27 Sep 2020 14:35:18
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	27 Sep 2020 14:35:18

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:33:55', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9da118e2-87ea-4e45-ac1b-d92a24dc0b31'	System	27 Sep 2020 14:35:18
User entered 'Yes (Y)'	System	27 Sep 2020 14:35:18

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:34:20', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9da118e2-87ea-4e45-ac1b-d92a24dc0b31'	System	27 Sep 2020 14:35:18
User entered '100'	System	27 Sep 2020 14:35:18

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:34:27', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9da118e2-87ea-4e45-ac1b-d92a24dc0b31'	System	27 Sep 2020 14:35:18
User entered 'Yes (Y)'	System	27 Sep 2020 14:35:18

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:34:37', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9da118e2-87ea-4e45-ac1b-d92a24dc0b31'	System	27 Sep 2020 14:35:18
User entered '100'	System	27 Sep 2020 14:35:18

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:35:08', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9da118e2-87ea-4e45-ac1b-d92a24dc0b31'	System	27 Sep 2020 14:35:18
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	27 Sep 2020 14:35:18

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:35:12', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9da118e2-87ea-4e45-ac1b-d92a24dc0b31'	System	27 Sep 2020 14:35:18
User entered '27 Sep 2020 10:35'	System	27 Sep 2020 14:35:18

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 4'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:00:27', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a8ceeb06-f461-4ad0-a402-26c898d0bc9b'	System	28 Sep 2020 02:01:39
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	28 Sep 2020 02:01:39

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:00:31', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a8ceeb06-f461-4ad0-a402-26c898d0bc9b'	System	28 Sep 2020 02:01:39
User entered 'Yes (Y)'	System	28 Sep 2020 02:01:39

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:00:57', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a8ceeb06-f461-4ad0-a402-26c898d0bc9b' User entered '2'	System	28 Sep 2020 02:01:39

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:01:03', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a8ceeb06-f461-4ad0-a402-26c898d0bc9b'	System	28 Sep 2020 02:01:39
User entered 'Yes (Y)'	System	28 Sep 2020 02:01:39

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:01:22', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a8ceeb06-f461-4ad0-a402-26c898d0bc9b'	System	28 Sep 2020 02:01:39
User entered '200'	System	28 Sep 2020 02:01:39

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:01:30', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a8ceeb06-f461-4ad0-a402-26c898d0bc9b'	System	28 Sep 2020 02:01:39
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	28 Sep 2020 02:01:39

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:01:36', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'a8ceeb06-f461-4ad0-a402-26c898d0bc9b'	System	28 Sep 2020 02:01:39
User entered '27 Sep 2020 22:01'	System	28 Sep 2020 02:01:39

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 5'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:50:43', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5961e99a-3dfa-4ef1-b9e4-7da829425005'	System	28 Sep 2020 21:51:46
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	28 Sep 2020 21:51:46

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:50:48', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5961e99a-3dfa-4ef1-b9e4-7da829425005'	System	28 Sep 2020 21:51:46
User entered 'Yes (Y)'	System	28 Sep 2020 21:51:46

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:50:54', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5961e99a-3dfa-4ef1-b9e4-7da829425005'	System	28 Sep 2020 21:51:46
User entered '200'	System	28 Sep 2020 21:51:46

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:50:59', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5961e99a-3dfa-4ef1-b9e4-7da829425005'	System	28 Sep 2020 21:51:46
User entered 'Yes (Y)'	System	28 Sep 2020 21:51:46

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:51:11', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5961e99a-3dfa-4ef1-b9e4-7da829425005'	System	28 Sep 2020 21:51:46
User entered '200'	System	28 Sep 2020 21:51:46

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:51:18', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5961e99a-3dfa-4ef1-b9e4-7da829425005'	System	28 Sep 2020 21:51:46
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	28 Sep 2020 21:51:46

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:51:21', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5961e99a-3dfa-4ef1-b9e4-7da829425005'	System	28 Sep 2020 21:51:46
User entered '28 Sep 2020 17:51'	System	28 Sep 2020 21:51:46

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 6'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:14:52', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '988cda8e-e246-42d6-a00e-13fbdbbdf02'	System	30 Sep 2020 00:15:38
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	30 Sep 2020 00:15:38

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:15:01', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '988cda8e-e246-42d6-a00e-13fbebdf02'	System	30 Sep 2020 00:15:38
User entered 'No (N)'	System	30 Sep 2020 00:15:38

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:15:14', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '988cda8e-e246-42d6-a00e-13fbebdf02'	System	30 Sep 2020 00:15:38
User entered 'Yes (Y)'	System	30 Sep 2020 00:15:38

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:15:23', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '988cda8e-e246-42d6-a00e-13fbebdf02'	System	30 Sep 2020 00:15:38
User entered '200'	System	30 Sep 2020 00:15:38

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:15:31', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '988cda8e-e246-42d6-a00e-13fbdbbdf02'	System	30 Sep 2020 00:15:38
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 00:15:38

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:15:33', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '988cda8e-e246-42d6-a00e-13fbebdf02'	System	30 Sep 2020 00:15:38
User entered '29 Sep 2020 20:15'	System	30 Sep 2020 00:15:38

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 7'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:06', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9bbd9575-8a77-4096-a6ad-1cb450518618'	System	30 Sep 2020 23:02:25
User entered 'None (1)'	System	30 Sep 2020 23:02:25

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:10', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9bbd9575-8a77-4096-a6ad-1cb450518618'	System	30 Sep 2020 23:02:25
User entered 'No (N)'	System	30 Sep 2020 23:02:25

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:13', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9bbd9575-8a77-4096-a6ad-1cb450518618'	System	30 Sep 2020 23:02:25
User entered 'No (N)'	System	30 Sep 2020 23:02:25

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:19', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9bbd9575-8a77-4096-a6ad-1cb450518618'	System	30 Sep 2020 23:02:25
User entered 'None (1)'	System	30 Sep 2020 23:02:25

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:22', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '9bbd9575-8a77-4096-a6ad-1cb450518618'	System	30 Sep 2020 23:02:25
User entered '30 Sep 2020 19:02'	System	30 Sep 2020 23:02:25

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:31:01', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '8f2335dd-6ee3-4a01-b1cd-8741ff8f06be'	System	24 Sep 2020 16:31:27
User entered 'None (0)'	System	24 Sep 2020 16:31:27

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:31:04', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '8f2335dd-6ee3-4a01-b1cd-8741ff8f06be'	System	24 Sep 2020 16:31:27
User entered 'None (0)'	System	24 Sep 2020 16:31:27

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:31:07', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '8f2335dd-6ee3-4a01-b1cd-8741ff8f06be'	System	24 Sep 2020 16:31:27
User entered 'None (0)'	System	24 Sep 2020 16:31:27

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:31:11', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '8f2335dd-6ee3-4a01-b1cd-8741ff8f06be'	System	24 Sep 2020 16:31:27
User entered 'None (0)'	System	24 Sep 2020 16:31:27

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:31:14', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '8f2335dd-6ee3-4a01-b1cd-8741ff8f06be'	System	24 Sep 2020 16:31:27
User entered 'None (0)'	System	24 Sep 2020 16:31:27

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:31:17', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '8f2335dd-6ee3-4a01-b1cd-8741ff8f06be'	System	24 Sep 2020 16:31:27
User entered 'None (0)'	System	24 Sep 2020 16:31:27

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:31:22', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '8f2335dd-6ee3-4a01-b1cd-8741ff8f06be'	System	24 Sep 2020 16:31:27
User entered 'No (N)'	System	24 Sep 2020 16:31:27

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T12:31:25', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '8f2335dd-6ee3-4a01-b1cd-8741ff8f06be'	System	24 Sep 2020 16:31:27
User entered '24 Sep 2020 12:31'	System	24 Sep 2020 16:31:27

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '24 Sep 2020 12:18'	System	24 Sep 2020 16:08:55
User entered '17 Sep 2020 11:51'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '24 Sep 2020 14:48'	System	24 Sep 2020 16:08:55
User entered '17 Sep 2020 14:21'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:22', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7eab11c4-ddd4-422a-8db3-77f5329060d4'	System	24 Sep 2020 19:44:57
User entered 'None (0)'	System	24 Sep 2020 19:44:57

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:24', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7eab11c4-ddd4-422a-8db3-77f5329060d4'	System	24 Sep 2020 19:44:57
User entered 'None (0)'	System	24 Sep 2020 19:44:57

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:29', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7eab11c4-ddd4-422a-8db3-77f5329060d4' User entered 'None (0)'	System	24 Sep 2020 19:44:57
	System	24 Sep 2020 19:44:57

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:34', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7eab11c4-ddd4-422a-8db3-77f5329060d4' User entered 'None (0)'	System	24 Sep 2020 19:44:57

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:37', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7eab11c4-ddd4-422a-8db3-77f5329060d4' User entered 'None (0)'	System	24 Sep 2020 19:44:57
	System	24 Sep 2020 19:44:57

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:41', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7eab11c4-ddd4-422a-8db3-77f5329060d4' User entered 'None (0)'	System	24 Sep 2020 19:44:57
	System	24 Sep 2020 19:44:57

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:48', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7eab11c4-ddd4-422a-8db3-77f5329060d4'	System	24 Sep 2020 19:44:57
User entered 'No (N)'	System	24 Sep 2020 19:44:57

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-24T15:44:52', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '7eab11c4-ddd4-422a-8db3-77f5329060d4'	System	24 Sep 2020 19:44:57
User entered '24 Sep 2020 15:44'	System	24 Sep 2020 19:44:57

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '24 Sep 2020 15:43'	System	24 Sep 2020 16:08:55
User entered '17 Sep 2020 15:16'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 2'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 3'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:35:26', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd328650d-497b-49f3-8861-af37e02e0557'	System	27 Sep 2020 14:36:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	27 Sep 2020 14:36:55

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:35:34', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd328650d-497b-49f3-8861-af37e02e0557'	System	27 Sep 2020 14:36:55
User entered 'None (0)'	System	27 Sep 2020 14:36:55

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:35:47', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd328650d-497b-49f3-8861-af37e02e0557'	System	27 Sep 2020 14:36:55
User entered 'Significant; prevents daily activity (3)'	System	27 Sep 2020 14:36:55

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:35:53', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd328650d-497b-49f3-8861-af37e02e0557'	System	27 Sep 2020 14:36:55
User entered 'Significant; prevents daily activity (3)'	System	27 Sep 2020 14:36:55

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:36:02', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd328650d-497b-49f3-8861-af37e02e0557'	System	27 Sep 2020 14:36:55
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	27 Sep 2020 14:36:55

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:36:12', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd328650d-497b-49f3-8861-af37e02e0557'	System	27 Sep 2020 14:36:55
User entered 'Some interference with activity not requiring medical attention (2)'	System	27 Sep 2020 14:36:55

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:36:49', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd328650d-497b-49f3-8861-af37e02e0557'	System	27 Sep 2020 14:36:55
User entered 'No (N)'	System	27 Sep 2020 14:36:55

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T10:36:52', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd328650d-497b-49f3-8861-af37e02e0557' User entered '27 Sep 2020 10:36'	System	27 Sep 2020 14:36:55
	System	27 Sep 2020 14:36:55

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 4'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:01:42', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '750ac950-10e8-4568-8005-43e1d43ed66b'	System	28 Sep 2020 02:02:31
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	28 Sep 2020 02:02:31

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:01:50', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '750ac950-10e8-4568-8005-43e1d43ed66b'	System	28 Sep 2020 02:02:31
User entered 'Some interference with activity (2)'	System	28 Sep 2020 02:02:31

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:01:55', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '750ac950-10e8-4568-8005-43e1d43ed66b'	System	28 Sep 2020 02:02:31
User entered 'Some interference with activity (2)'	System	28 Sep 2020 02:02:31

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:02:03', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '750ac950-10e8-4568-8005-43e1d43ed66b'	System	28 Sep 2020 02:02:31
User entered 'Some interference with activity (2)'	System	28 Sep 2020 02:02:31

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:02:13', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '750ac950-10e8-4568-8005-43e1d43ed66b'	System	28 Sep 2020 02:02:31
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Sep 2020 02:02:31

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:02:20', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '750ac950-10e8-4568-8005-43e1d43ed66b'	System	28 Sep 2020 02:02:31
User entered 'Some interference with activity not requiring medical attention (2)'	System	28 Sep 2020 02:02:31

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:02:26', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '750ac950-10e8-4568-8005-43e1d43ed66b'	System	28 Sep 2020 02:02:31
User entered 'No (N)'	System	28 Sep 2020 02:02:31

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-27T22:02:30', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '750ac950-10e8-4568-8005-43e1d43ed66b'	System	28 Sep 2020 02:02:31
User entered '27 Sep 2020 22:02'	System	28 Sep 2020 02:02:31

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 5'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:51:27', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e437f874-038a-4b28-9cf3-0711506da99b'	System	28 Sep 2020 21:52:33
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	28 Sep 2020 21:52:33

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:51:32', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e437f874-038a-4b28-9cf3-0711506da99b'	System	28 Sep 2020 21:52:33
User entered 'Some interference with activity (2)'	System	28 Sep 2020 21:52:33

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:51:43', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e437f874-038a-4b28-9cf3-0711506da99b'	System	28 Sep 2020 21:52:33
User entered 'Significant; prevents daily activity (3)'	System	28 Sep 2020 21:52:33

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:51:50', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e437f874-038a-4b28-9cf3-0711506da99b'	System	28 Sep 2020 21:52:33
User entered 'Significant; prevents daily activity (3)'	System	28 Sep 2020 21:52:33

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:52:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e437f874-038a-4b28-9cf3-0711506da99b'	System	28 Sep 2020 21:52:33
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Sep 2020 21:52:33

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:52:06', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e437f874-038a-4b28-9cf3-0711506da99b'	System	28 Sep 2020 21:52:33
User entered 'Some interference with activity not requiring medical attention (2)'	System	28 Sep 2020 21:52:33

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:52:12', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e437f874-038a-4b28-9cf3-0711506da99b'	System	28 Sep 2020 21:52:33
User entered 'No (N)'	System	28 Sep 2020 21:52:33

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-28T17:52:16', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'e437f874-038a-4b28-9cf3-0711506da99b'	System	28 Sep 2020 21:52:33
User entered '28 Sep 2020 17:52'	System	28 Sep 2020 21:52:33

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 6'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:15:41', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b5b3fffc-a79f-41d7-901c-7dc8b6bd20d2'	System	30 Sep 2020 00:16:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:15:46', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b5b3fffc-a79f-41d7-901c-7dc8b6bd20d2'	System	30 Sep 2020 00:16:30
User entered 'No interference with activity (1)'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:15:58', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b5b3fffc-a79f-41d7-901c-7dc8b6bd20d2'	System	30 Sep 2020 00:16:30
User entered 'Some interference with activity (2)'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:16:04', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b5b3fffc-a79f-41d7-901c-7dc8b6bd20d2'	System	30 Sep 2020 00:16:30
User entered 'Some interference with activity (2)'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:16:09', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b5b3fffc-a79f-41d7-901c-7dc8b6bd20d2'	System	30 Sep 2020 00:16:30
User entered 'None (0)'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:16:13', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b5b3fffc-a79f-41d7-901c-7dc8b6bd20d2'	System	30 Sep 2020 00:16:30
User entered 'None (0)'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:16:23', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b5b3fffc-a79f-41d7-901c-7dc8b6bd20d2'	System	30 Sep 2020 00:16:30
User entered 'No (N)'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-29T20:16:25', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'b5b3fffc-a79f-41d7-901c-7dc8b6bd20d2'	System	30 Sep 2020 00:16:30
User entered '29 Sep 2020 20:16'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	17 Sep 2020 15:36:47
User entered 'Day 7'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:29', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fc909017-e24f-4e35-938b-61c100e87828'	System	30 Sep 2020 23:03:00
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:32', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fc909017-e24f-4e35-938b-61c100e87828'	System	30 Sep 2020 23:03:00
User entered 'Some interference with activity (2)'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:36', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fc909017-e24f-4e35-938b-61c100e87828'	System	30 Sep 2020 23:03:00
User entered 'Some interference with activity (2)'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:40', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fc909017-e24f-4e35-938b-61c100e87828'	System	30 Sep 2020 23:03:00
User entered 'Some interference with activity (2)'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:44', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fc909017-e24f-4e35-938b-61c100e87828'	System	30 Sep 2020 23:03:00
User entered 'None (0)'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:47', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fc909017-e24f-4e35-938b-61c100e87828'	System	30 Sep 2020 23:03:00
User entered 'None (0)'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:53', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fc909017-e24f-4e35-938b-61c100e87828'	System	30 Sep 2020 23:03:00
User entered 'No (N)'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-09-30T19:02:55', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'fc909017-e24f-4e35-938b-61c100e87828'	System	30 Sep 2020 23:03:00
User entered '30 Sep 2020 19:02'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:08:55
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:08:55
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:36:47

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	30 Sep 2020 00:16:30
User entered 'Day 8'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	30 Sep 2020 23:03:00
User entered 'Day 9'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	30 Sep 2020 00:16:30
User entered 'Day 8'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	30 Sep 2020 23:03:00
User entered 'Day 9'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	30 Sep 2020 00:16:30
User entered 'Day 8'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	30 Sep 2020 23:03:00
User entered 'Day 9'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	30 Sep 2020 00:16:30
User entered 'Day 8'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 00:16:30

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	30 Sep 2020 23:03:00
User entered 'Day 9'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	30 Sep 2020 00:15:38
User entered 'Day 8'	System	30 Sep 2020 00:15:38

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 00:15:38

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 00:15:38

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	30 Sep 2020 23:03:00
User entered 'Day 9'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:35:42

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 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 23:03:00

US3172322

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:35:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 23:03:00

US3172322

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 17:48:06

US3172322

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '1 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 17:48:06

US3172322

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 17:48:06

US3172322

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 17:48:06

US3172322

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:06:56
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 20:01:42
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 17:48:10

US3172322

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User entered '1'	System	16 Oct 2020 23:06:56
User entered empty.	System	06 Oct 2020 20:01:42
User entered '1'	System	06 Oct 2020 17:48:10

US3172322

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:07:19

US3172322

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '08 Oct 2020'	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:07:19

US3172322

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:07:19

US3172322

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:07:19

US3172322

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:07:24

US3172322

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User entered 'I'	System	16 Oct 2020 23:07:24

US3172322

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:07:39

US3172322

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:59:20
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Data correct as entered.' (Site from System).	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:07:58
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Oct 2020 23:07:39
User entered '14 Oct 2020'	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:07:39

US3172322

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:07:39

US3172322

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:07:39

US3172322

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 20:32:26
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 23:08:03

US3172322

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User entered '1'	System	18 Nov 2020 20:32:26
User entered empty.	System	16 Oct 2020 23:08:03

US3172322

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:05

US3172322

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:05

US3172322

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:05

US3172322

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'VISIT3'	System	22 Dec 2020 20:51:05

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered empty.	System	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered empty.	System	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered empty.	System	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered empty.	System	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered empty.	System	22 Dec 2020 20:51:11

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51

US3172322

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51

US3172322

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:15

US3172322

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:15

US3172322

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:20

US3172322

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:20

US3172322

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:51:20

US3172322

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered empty.	System	22 Dec 2020 20:51:20

US3172322

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 19:44:34

US3172322

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User entered 'I'	System	22 Dec 2020 19:44:34

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 64'	System	25 Aug 2020 19:26:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50
Data entry locked.	System	25 Aug 2020 19:26:59
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 19:26:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:50
Data entry locked.	System	25 Aug 2020 19:26:59
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 71'	System	25 Aug 2020 19:26:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-11-05T13:48:18', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '4ca868a8-7fc9-424b-98f3-ba238943268d'	System	05 Nov 2020 18:48:27
User entered 'No (N)'	System	05 Nov 2020 18:48:27

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-11-05T13:48:08', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '4ca868a8-7fc9-424b-98f3-ba238943268d'	System	05 Nov 2020 18:48:27
User entered 'No (N)'	System	05 Nov 2020 18:48:27

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-11-05T13:48:24', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '4ca868a8-7fc9-424b-98f3-ba238943268d'	System	05 Nov 2020 18:48:27
User entered '05 Nov 2020 13:48:24'	System	05 Nov 2020 18:48:27

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 19:26:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered 'Day 78'	System	25 Aug 2020 19:26:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-11-11T15:13:47', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1110e29b-ef9f-430e-a416-3238379ef344'	System	11 Nov 2020 20:13:59
User entered 'No (N)'	System	11 Nov 2020 20:13:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-11-11T15:13:49', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1110e29b-ef9f-430e-a416-3238379ef344'	System	11 Nov 2020 20:13:59
User entered 'No (N)'	System	11 Nov 2020 20:13:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-11-11T15:13:54', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '1110e29b-ef9f-430e-a416-3238379ef344'	System	11 Nov 2020 20:13:59
User entered '11 Nov 2020 15:13:54'	System	11 Nov 2020 20:13:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 19:26:59

US3172322

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:55:26
Data entry locked.	System	25 Aug 2020 19:26:59
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 19:26:59

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (d47095247b1411ac)', Time: '2020-12-11T17:46:29', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '0167026b-8097-40d3-9aef-75eb01637706'	System	11 Dec 2020 22:46:50
User entered 'No (N)'	System	11 Dec 2020 22:46:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Have you been exposed to someone with 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 (d47095247b1411ac)', Time: '2020-12-11T17:46:36', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '0167026b-8097-40d3-9aef-75eb01637706'	System	11 Dec 2020 22:46:50
User entered 'No (N)'	System	11 Dec 2020 22:46:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-12-11T17:46:46', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '0167026b-8097-40d3-9aef-75eb01637706'	System	11 Dec 2020 22:46:50
User entered '11 Dec 2020 17:46:46'	System	11 Dec 2020 22:46:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (d47095247b1411ac)', Time: '2020-12-19T04:07:17', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd14cd7c1-5e90-4c3f-8ccb-9fed58a5d7b7'	System	19 Dec 2020 09:07:35
User entered 'No (N)'	System	19 Dec 2020 09:07:35

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Have you been exposed to someone with 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 (d47095247b1411ac)', Time: '2020-12-19T04:07:26', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd14cd7c1-5e90-4c3f-8ccb-9fed58a5d7b7'	System	19 Dec 2020 09:07:35
User entered 'No (N)'	System	19 Dec 2020 09:07:35

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-12-19T04:07:31', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd14cd7c1-5e90-4c3f-8ccb-9fed58a5d7b7' User entered '19 Dec 2020 04:07:31'	System	19 Dec 2020 09:07:35
	System	19 Dec 2020 09:07:35

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (d47095247b1411ac)', Time: '2020-12-24T15:46:11', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5a517049-3f14-4a3c-842b-47424daa29b4'	System	24 Dec 2020 20:46:39
User entered 'No (N)'	System	24 Dec 2020 20:46:39

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Have you been exposed to someone with 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 (d47095247b1411ac)', Time: '2020-12-24T15:46:18', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5a517049-3f14-4a3c-842b-47424daa29b4'	System	24 Dec 2020 20:46:39
User entered 'No (N)'	System	24 Dec 2020 20:46:39

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2020-12-24T15:46:37', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '5a517049-3f14-4a3c-842b-47424daa29b4'	System	24 Dec 2020 20:46:39
User entered '24 Dec 2020 15:46:37'	System	24 Dec 2020 20:46:39

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (d47095247b1411ac)', Time: '2021-01-11T12:45:44', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '06c5050e-ce9b-4cc0-a336-b5a165681773'	System	11 Jan 2021 17:46:13
User entered 'No (N)'	System	11 Jan 2021 17:46:13

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Have you been exposed to someone with 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 (d47095247b1411ac)', Time: '2021-01-11T12:45:52', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '06c5050e-ce9b-4cc0-a336-b5a165681773'	System	11 Jan 2021 17:46:13
User entered 'No (N)'	System	11 Jan 2021 17:46:13

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2021-01-11T12:46:08', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '06c5050e-ce9b-4cc0-a336-b5a165681773'	System	11 Jan 2021 17:46:13
User entered '11 Jan 2021 12:46:08'	System	11 Jan 2021 17:46:13

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (d47095247b1411ac)', Time: '2021-01-14T04:54:35', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '72641e6e-b527-4e1b-9723-26af68c8e6a3'	System	14 Jan 2021 09:54:54
User entered 'No (N)'	System	14 Jan 2021 09:54:54

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Have you been exposed to someone with 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 (d47095247b1411ac)', Time: '2021-01-14T04:54:41', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '72641e6e-b527-4e1b-9723-26af68c8e6a3'	System	14 Jan 2021 09:54:54
User entered 'No (N)'	System	14 Jan 2021 09:54:54

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d47095247b1411ac)', Time: '2021-01-14T04:54:50', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '72641e6e-b527-4e1b-9723-26af68c8e6a3' User entered '14 Jan 2021 04:54:50'	System	14 Jan 2021 09:54:54

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (0edfbc6752d4fe23)', Time: '2021-03-25T14:11:18-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'dbcdb35-2b17-49cc-955b-d3b1b9d41636'	System	25 Mar 2021 18:11:40
User entered 'No (N)'	System	25 Mar 2021 18:11:40

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Have you been exposed to someone with 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 (0edfbc6752dafa23)', Time: '2021-03-25T14:11:25-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'dbcdb35-2b17-49cc-955b-d3b1b9d41636'	System	25 Mar 2021 18:11:40
User entered 'No (N)'	System	25 Mar 2021 18:11:40

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0edfbc6752d4fe23)', Time: '2021-03-25T14:11:37-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'dbcdb35-2b17-49cc-955b-d3b1b9d41636'	System	25 Mar 2021 18:11:40
User entered '25 Mar 2021 14:11:37'	System	25 Mar 2021 18:11:40

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (0edfbc6752dafa23)', Time: '2021-04-01T20:57:25-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '95aba4c7-05e0-495b-a5dd-1f4f03950ac3' User entered 'No (N)'	System	02 Apr 2021 00:57:55
	System	02 Apr 2021 00:57:55

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Have you been exposed to someone with 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 (0edfbc6752dafa23)', Time: '2021-04-01T20:57:31-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '95aba4c7-05e0-495b-a5dd-1f4f03950ac3'	System	02 Apr 2021 00:57:55
User entered 'No (N)'	System	02 Apr 2021 00:57:55

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0edfbc6752dafa23)', Time: '2021-04-01T20:57:50-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '95aba4c7-05e0-495b-a5dd-1f4f03950ac3' User entered '01 Apr 2021 20:57:50'	System	02 Apr 2021 00:57:55
	System	02 Apr 2021 00:57:55

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (0edfbc6752dafa23)', Time: '2021-04-11T22:38:56-05:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd4ad3220-04df-4eee-b011-5bd912cf153b'	System	12 Apr 2021 03:39:16
User entered 'No (N)'	System	12 Apr 2021 03:39:16

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Have you been exposed to someone with 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 (0edfbc6752dafa23)', Time: '2021-04-11T22:39:03-05:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd4ad3220-04df-4eee-b011-5bd912cf153b'	System	12 Apr 2021 03:39:16
User entered 'No (N)'	System	12 Apr 2021 03:39:16

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0edfbc6752dafa23)', Time: '2021-04-11T22:39:09-05:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'd4ad3220-04df-4eee-b011-5bd912cf153b'	System	12 Apr 2021 03:39:16
User entered '11 Apr 2021 22:39:09'	System	12 Apr 2021 03:39:16

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (0edfbc6752dafa23)', Time: '2021-04-15T00:39:33-05:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '330b35ef-04ca-4915-97df-74e405781ff2'	System	15 Apr 2021 05:40:06
User entered 'No (N)'	System	15 Apr 2021 05:40:06

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Have you been exposed to someone with 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 (0edfbc6752dafa23)', Time: '2021-04-15T00:39:45-05:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '330b35ef-04ca-4915-97df-74e405781ff2'	System	15 Apr 2021 05:40:06
User entered 'No (N)'	System	15 Apr 2021 05:40:06

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0edfbc6752dafa23)', Time: '2021-04-15T00:40:01-05:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '330b35ef-04ca-4915-97df-74e405781ff2'	System	15 Apr 2021 05:40:06
User entered '15 Apr 2021 00:40:01'	System	15 Apr 2021 05:40:06

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (0edfbc6752dafa23)', Time: '2021-04-22T00:21:13-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '95be4e1d-66df-4be7-be16-4d03c92e0c8b' User entered 'No (N)'	System	22 Apr 2021 04:21:30
	System	22 Apr 2021 04:21:30

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Have you been exposed to someone with 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 (0edfbc6752dafa23)', Time: '2021-04-22T00:21:18-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '95be4e1d-66df-4be7-be16-4d03c92e0c8b' User entered 'No (N)'	System	22 Apr 2021 04:21:30
	System	22 Apr 2021 04:21:30

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0edfbc6752dafa23)', Time: '2021-04-22T00:21:26-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '95be4e1d-66df-4be7-be16-4d03c92e0c8b' User entered '22 Apr 2021 00:21:26'	System	22 Apr 2021 04:21:30
	System	22 Apr 2021 04:21:30

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[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 (0edfbc6752dafa23)', Time: '2021-04-29T02:05:08-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'c5abc64c-27e8-40d5-ab86-abf9bbf18e18'	System	29 Apr 2021 06:05:32
User entered 'No (N)'	System	29 Apr 2021 06:05:32

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

Have you been exposed to someone with 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 (0edfbc6752d4fe23)', Time: '2021-04-29T02:05:14-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'c5abc64c-27e8-40d5-ab86-abf9bbf18e18'	System	29 Apr 2021 06:05:32
User entered 'No (N)'	System	29 Apr 2021 06:05:32

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0edfbc6752dafa23)', Time: '2021-04-29T02:05:28-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: 'c5abc64c-27e8-40d5-ab86-abf9bbf18e18'	System	29 Apr 2021 06:05:32
User entered '29 Apr 2021 02:05:28'	System	29 Apr 2021 06:05:32

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 17:30:50

US3172322

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:50
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 17:30:50

US3172322

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:35:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0edfbc6752d4fe23)', Time: '2021-03-23T13:08:24-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '0ab3dfb2-d42c-47d7-9a10-d153ed25a619'	System	23 Mar 2021 17:10:37
User entered 'No (N)'	System	23 Mar 2021 17:10:37

US3172322

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:35:42

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0edfbc6752d4fe23)', Time: '2021-03-23T13:08:39-04:00', User OID: 'PatientReportedOutcome (US3172322)', ODM File OID: '0ab3dfb2-d42c-47d7-9a10-d153ed25a619' User entered '23 Mar 2021 13:08:39'	System	23 Mar 2021 17:10:37
	System	23 Mar 2021 17:10:37

US3172322

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 19:44:55

US3172322

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '18 Nov 2020'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 19:44:55

US3172322

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 19:44:55

US3172322

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 19:44:55

US3172322

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 19:45:00

US3172322

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:45:47
User entered 'I'	System	22 Dec 2020 19:45:00

US3172322

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 19:45:12

US3172322

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '22 Dec 2020'	Jessie Downs (b) (4)	22 Dec 2020 19:45:12
	(b) (4)	

US3172322

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	22 Dec 2020 19:45:12
	(b) (4)	

US3172322

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 19:45:12

US3172322

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Dec 2020 19:45:16

US3172322

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User entered 'I'	System	22 Dec 2020 19:45:16

US3172322

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 21:16:17

US3172322

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 21:16:17

US3172322

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 21:16:17

US3172322

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'unable to contact subject. no voicemail set up.'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 21:16:17

US3172322

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Jan 2021 21:16:20

US3172322

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User entered 'I'	System	25 Jan 2021 21:16:20

US3172322

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 21:59:50

US3172322

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered '24 Feb 2021'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 21:59:50

US3172322

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 21:59:50

US3172322

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered 'unable to contact subject. phone is not in service.'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 21:59:50

US3172322

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 21:59:55

US3172322

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:25:38
User entered 'I'	System	24 Feb 2021 21:59:55

US3172322

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:00:54

US3172322

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:00:54

US3172322

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[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 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:00:54

US3172322

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	28 Apr 2021 15:00:54

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:01:02

US3172322

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:08

US3172322

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:08

US3172322

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:14

US3172322

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:14

US3172322

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 22:26:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	28 Apr 2021 15:01:14

US3172322

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 15:01:14

US3172322

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:30:40

US3172322

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 14:30:40

US3172322

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:31:00

US3172322

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered '21 Apr 2021'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:31:00

US3172322

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:31:00

US3172322

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered empty.	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:31:00

US3172322

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:31:23

US3172322

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:42

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 14:31:23

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:35:42

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '29 Sep 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:48:31

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:35:42

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '12:00'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:48:31

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:35:42

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User entered '29 Sep 2020 12:00'	System	28 Oct 2020 13:48:31

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:35:42

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:48:31

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:35:42

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:48:31

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Day 1 (Day 1)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '26 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User closed query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-5 and Temperature for Days 1, 2, 3 and 5. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:07:51
Query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-5 and Temperature for Days 1, 2, 3 and 5. If not collected, please consider recording these as NOT DONE' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 15:57:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 15:57:31
User opened query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-5 and Temperature for Days 1, 2, 3 and 5. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 11:18:33
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User entered '%'	System	07 Jan 2021 15:57:31
User entered empty.	System	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 15:57:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:35:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:56:54

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Day 2 (Day 2)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '27 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 15:57:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User entered '%'	System	07 Jan 2021 15:57:31
User entered empty.	System	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 15:57:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:35:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:05

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Day 3 (Day 3)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '28 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 15:57:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User entered '%'	System	07 Jan 2021 15:57:31
User entered empty.	System	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 15:57:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:35:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:57:16

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Day 4 (Day 4)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '29 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 15:57:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User entered '%'	System	07 Jan 2021 15:57:31
User entered empty.	System	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '36.9' C reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:35:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:30

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Day 5 (Day 5)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '30 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 15:57:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User entered '%'	System	07 Jan 2021 15:57:31
User entered empty.	System	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 15:57:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:35:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 17:32:43
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 16:58:40

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:35:42

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '29 Sep 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:12

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:35:42

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 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:12

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:35:42

[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 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:12

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:35:42

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '29 Sep 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:12

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Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:35:42

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:12

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:35:42

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:12

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:35:42

[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 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:12

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:35:42

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:12

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:35:42

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:12

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:35:42

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User entered '0'	System	28 Oct 2020 13:50:12

US3172322

Folder: Covid-19 Assessment 29 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:35:42

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:16

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:35:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:35:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Dec 2020 21:53:19
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	06 Nov 2020 20:10:41
	(b) (4)	

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:35:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User closed query 'Per GCL LAB reconciliation: Saliva: Requery 1: Please confirm if the sample was shipped to Lab, if yes, kindly provide the accession number/tracking details whichever available.Thanks ? ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 10:55:37
Query 'Per GCL LAB reconciliation: Saliva: Requery 1: Please confirm if the sample was shipped to Lab, if yes, kindly provide the accession number/tracking details whichever available.Thanks ? ' answered with 'Accession #: 1F602216492. Tracking #: 914897890462. Tracking #: 914897890690.' (Site from DM).	Jessie Downs (b) (4)	27 Jan 2021 16:01:14
	(b) (4)	
User opened query 'Per GCL LAB reconciliation: Saliva: Requery 1: Please confirm if the sample was shipped to Lab, if yes, kindly provide the accession number/tracking details whichever available.Thanks ? ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:10:41
User closed query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 29SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:10:41
Query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 29SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'illness day 1 for subject 2322 was collected 29sep20.' (Site from DM).	Jessie Downs (b) (4)	11 Jan 2021 18:25:23
	(b) (4)	
User opened query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 29SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 04:15:57
User entered '29 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Dec 2020 21:53:19
	(b) (4)	

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:35:42

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:35:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:35:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:35:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:35:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:35:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:35:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:35:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:35:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:35:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:35:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:35:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:35:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:35:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:35:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:35:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:35:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:35:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:35:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:10:41

US3172322

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:50:39

US3172322

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '29 Sep 2020'	Jessie Downs (b) (4)	28 Oct 2020 13:50:39
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[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 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4)	28 Oct 2020 13:50:39
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User entered 'SICKD1'	System	28 Oct 2020 13:50:39

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:55:51

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '29 Sep 2020'	Jessie Downs (b) (4)	28 Oct 2020 13:55:51
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '12:07'	Jessie Downs (b) (4)	28 Oct 2020 13:55:51
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User entered '29 Sep 2020 12:07'	System	28 Oct 2020 13:55:51

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '154.9' cm	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:55:51
DataPoint set to visible.	System	28 Oct 2020 13:50:39

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '097.2' kg	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:55:51
DataPoint set to visible.	System	28 Oct 2020 13:50:39

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '36.9' C	Jessie Downs (b) (4)	28 Oct 2020 13:55:51
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'Oral (Oral)'	Jessie Downs (b) (4)	28 Oct 2020 13:55:51
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	28 Oct 2020 13:55:51
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '70'	Jessie Downs (b) (4)	28 Oct 2020 13:55:51
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User entered 'bpm'	System	28 Oct 2020 13:55:51

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '14'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:55:51

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User entered 'breaths/min'	System	28 Oct 2020 13:55:51

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '138'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:55:51

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User entered 'mmHg'	System	28 Oct 2020 13:55:51

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '89'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:55:51

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User entered 'mmHg'	System	28 Oct 2020 13:55:51

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52

US3172322

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52

US3172322

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	28 Oct 2020 13:51:04
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '29 Sep 2020'	Jessie Downs (b) (4)	28 Oct 2020 13:51:04
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:35:42

[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 17:33:52
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	28 Oct 2020 13:51:15
	(b) (4)	

US3172322

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:35:42

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '29 Sep 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:51:15

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:32

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:32

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[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)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:32

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	02 Mar 2021 21:28:32

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 21:28:44

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:49

US3172322

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:49

US3172322

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:35:42

[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)	03 Mar 2021 13:58:50
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:54

US3172322

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:35:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:58:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 21:28:54

US3172322

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

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:35:01
	(b) (4)	
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	27 Apr 2021 14:11:16
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	27 Apr 2021 14:11:05
User entered 'Yes (Y)'	Jessie Downs (b) (4)	27 Apr 2021 14:11:05
	(b) (4)	

US3172322

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

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:35:01
	(b) (4)	
User entered '26 Apr 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	27 Apr 2021 14:11:16
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	27 Apr 2021 14:11:05
	(b) (4)	

US3172322

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

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:35:01
	(b) (4)	
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	27 Apr 2021 14:11:16
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Jessie Downs (b) (4)	27 Apr 2021 14:11:16
	(b) (4)	
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	27 Apr 2021 14:11:05
User entered empty.	Jessie Downs (b) (4)	27 Apr 2021 14:11:05
	(b) (4)	

US3172322

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

Form: Visit Date

Generated On: 09 Jun 2021 15:35:42

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	27 Apr 2021 14:11:05

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered '22 Dec 2020'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:29:39

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered '0'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:29:39

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:29:39

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:29:39

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered '26 Apr 2021'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:29:39

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:29:39

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:29:39

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:29:39

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:29:39

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 14:29:39

US3172322

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

Form: Unblinding

Generated On: 09 Jun 2021 15:35:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 14:29:39

US3172322

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:30:02

US3172322

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered '26 Apr 2021'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:30:02

US3172322

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered '12:46'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:30:02

US3172322

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Apr 2021 12:46'	System	27 Apr 2021 14:30:02

US3172322

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:30:18

US3172322

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered '26 Apr 2021'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:30:18

US3172322

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:01
User entered '12:47'	Jessie Downs (b) (4) (b) (4)	27 Apr 2021 14:30:18

US3172322

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:42

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Apr 2021 12:47'	System	27 Apr 2021 14:30:18

US3172322

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:35:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:37
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	12 Oct 2020 14:40:16
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	14 Sep 2020 14:19:44
	(b) (4)	

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Adverse event](#)

Audit	User	Time (GMT)
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 exacerbation - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:59:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:59:59
Data point term sent to Coder	System	24 Nov 2020 17:13:48
Coding entries removed.	Mariete Rendon (b) (4)	24 Nov 2020 17:13:27
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE Acute EXACERBATION' reason for change: Data Entry Error	Mariete Rendon (b) (4)	24 Nov 2020 17:13:27
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 exacerbation - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:47:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:47:24
Data point term sent to Coder	System	12 Oct 2020 14:46:41
User entered 'Chronic obstructive pulmonary disease exacerbation'	Mariete Rendon (b) (4)	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	12 Oct 2020 15:38:42
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	12 Oct 2020 15:38:42
User entered '07 Oct 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	12 Oct 2020 15:38:42
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	12 Oct 2020 14:46:37
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	12 Oct 2020 14:46:37
User entered '07 Jul 2020'	Mariete Rendon (b) (4)	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	15 Oct 2020 14:32:33
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 12:57:08
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Data correct as is. Subject A/E worsened. See SAE.' (Site from System).	Mariete Rendon (b) (4)	15 Oct 2020 18:46:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Oct 2020 14:32:33
User entered '10 Oct 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	15 Oct 2020 14:32:33
User entered empty.	(b) (4)	
	Mariete Rendon (b) (4)	12 Oct 2020 14:46:37
	(b) (4)	

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

Severity

Audit	User	Time (GMT)
User closed query 'Per DM CLR: RQ: Response noted, however, a worsening of a medical history condition should a have a grade of greater than 1/Mild. Please review grade and update as appropriate. Otherwise, review if this should be removed as an AE if appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:18:32
Query 'Per DM CLR: RQ: Response noted, however, a worsening of a medical history condition should a have a grade of greater than 1/Mild. Please review grade and update as appropriate. Otherwise, review if this should be removed as an AE if appropriate.'	Jessie Downs (b) (4)	26 Feb 2021 22:24:49
answered with 'Data confirmed as entered.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: RQ: Response noted, however, a worsening of a medical history condition should a have a grade of greater than 1/Mild. Please review grade and update as appropriate. Otherwise, review if this should be removed as an AE if appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:36:46
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.	(b) (4), (b) (6)	19 Nov 2020 19:33:55
' (Site from DM).		
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.	Jessie Downs (b) (4)	28 Oct 2020 13:42:30
' answered with 'Source verified. Grade 1 mild is correct as entered.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.	(b) (4), (b) (6)	26 Oct 2020 13:53:06
' (Site from DM).		
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	15 Oct 2020 14:32:33
	(b) (4)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mariete Rendon (b) (4)	12 Oct 2020 14:46:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:38:48
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4)	24 Nov 2020 17:14:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	24 Nov 2020 17:14:09
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:12:48
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	24 Nov 2020 17:14:09
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

Concomitant Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR re-query: Response noted. However, Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a conmed as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 06:14:24
Query 'Per DM CLR re-query: Response noted. However, Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a conmed as appropriate or update action taken.' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4)	03 Mar 2021 21:46:35
User opened query 'Per DM CLR re-query: Response noted. However, Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a conmed as appropriate or update action taken.' (Site from DM).	(b) (4)	02 Mar 2021 07:27:38
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of COPD. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:27:25
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of COPD. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' answered with 'medication was prescribed but not started. waiting on ER evaluation.' (Site from DM).	Jessie Downs (b) (4)	24 Feb 2021 22:09:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of COPD. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 06:08:58
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Oct 2020 14:46:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 14:46:37

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:07
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:34
User entered 'USA-US118-2020-mRNA-1273-P301000004'	System	16 Oct 2020 00:17:31
User entered 'New'	(b) (4), (b) (6)	16 Oct 2020 00:17:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Adverse event](#)

Audit	User	Time (GMT)
Query 'AE 1 and AE 2 need to be combined into 1 (site to void one of them).' canceled (Site from CRA).	(b) (4), (b) (6)	28 Apr 2021 13:15:50
User opened query 'AE 1 and AE 2 need to be combined into 1 (site to void one of them).' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:33:13
User closed query 'Per DM, Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates also reconciled. Therefore, one of the AEs should be removed and only 1 AE covering from 07Oct - 12Oct with severe grade should be left open.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:33:13
Query 'Per DM, Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates also reconciled. Therefore, one of the AEs should be removed and only 1 AE covering from 07Oct - 12Oct with severe grade should be left open.' answered with 'data confirmed as entered' (Site from CRA).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 22:25:36
User closed query 'Per DM CLR: Please note the start date of this AE overlaps with the end date of AE #1. Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 07:30:20
Query 'Per DM CLR: Please note the start date of this AE overlaps with the end date of AE #1. Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' answered with 'subject required hospitalization.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 22:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM, Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates also reconciled. Therefore, one of the AEs should be removed and only 1 AE covering from 07Oct - 12Oct with severe grade should be left open.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 19:54:32
User opened query 'Per DM CLR: Please note the start date of this AE overlaps with the end date of AE #1. Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 06:09:27
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 exacerbation - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 15:49:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 15:49:38
Data point term sent to Coder	System	15 Oct 2020 14:35:19
User entered 'Worsening of Chronic obstructive pulmonary disease'	Mariete Rendon (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	24 Nov 2020 17:11:26
User entered 'No (N)'	Mariete Rendon (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:14
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:16
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'no changes made. Please update and save.' canceled (Site from CRA).	(b) (4), (b) (6)	28 Apr 2021 13:15:58
User opened query 'no changes made. Please update and save.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:34:57
User closed query 'Both AEs/SAEs for COPD: exacerbation and worsening of exacerbation need to be combined into 1 SAE. Therefore, please void the first one recorded and update the start date here to 07Oct2020.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:34:57
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 22:28:51
User entered '10 Oct 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	26 Feb 2021 22:28:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 22:28:31
Query 'Both AEs/SAEs for COPD: exacerbation and worsening of exacerbation need to be combined into 1 SAE. Therefore, please void the first one recorded and update the start date here to 07Oct2020.' answered by data change (Site from CRA).	System	26 Feb 2021 22:28:31
User entered '10 2020' (non-conformant).	Jessie Downs (b) (4)	26 Feb 2021 22:28:31
User opened query 'Both AEs/SAEs for COPD: exacerbation and worsening of exacerbation need to be combined into 1 SAE. Therefore, please void the first one recorded and update the start date here to 07Oct2020.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 18:36:42
User entered '10 Oct 2020'	Mariete Rendon (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:37:14
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:21
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	24 Nov 2020 17:11:26
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:19
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 17:11:45
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	24 Nov 2020 17:11:45
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 17:11:26
User entered '12 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	24 Nov 2020 17:11:26
User entered empty.	Mariete Rendon (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:24
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:53:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:25:04
User entered empty.	System	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:26
User closed query 'PV Query: As the subject was admitted to the hospital, please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 18:19:00
Query 'PV Query: As the subject was admitted to the hospital, please consider updating the severity of the event to Grade 4.' answered with 'Data was updated.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 20:55:22
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 20:55:07
User opened query 'PV Query: As the subject was admitted to the hospital, please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:26:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:32
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	15 Oct 2020 14:37:50
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	15 Oct 2020 14:34:48
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:34
User entered '0'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:36
User entered '0'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 17:03:22
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Hospital discharge date will be provided when medical records are received.' (Site from System).	Jessie Downs (b) (4)	28 Oct 2020 20:56:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	15 Oct 2020 14:37:50
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	15 Oct 2020 14:37:50
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	15 Oct 2020 14:37:50
User entered '1' reason for change: Data Entry Error	Mariete Rendon (b) (4)	15 Oct 2020 14:37:50
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	15 Oct 2020 14:37:28
User entered '0'	System	
	Mariete Rendon (b) (4)	15 Oct 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 22:28:38
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:44
User entered '10 Oct 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	15 Oct 2020 14:37:28
User entered empty.	(b) (4)	
	Mariete Rendon (b) (4)	15 Oct 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 22:30:12
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 22:28:52
User opened query 'PER SAE RECON: Hospital discharge date missing. Kindly review and update.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 13:53:38
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:43:27
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 22:25:48
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:36:18
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 18:19:09
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Hospital discharge date will be provided once medical records are received.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 20:58:02
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:25:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:54
User entered '0'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:56
User entered '0'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:55:58
User entered '0'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:56:04
User closed query 'PV Query: Please provide missing causality assessment for the event and study procedure as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:26:06
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:39:20
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	24 Nov 2020 17:12:10
Query 'PV Query: Please provide missing causality assessment for the event and study procedure as soon as possible.' answered with 'Data updated' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	24 Nov 2020 17:11:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	24 Nov 2020 17:11:26
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:13:05
User opened query 'PV Query: Please provide missing causality assessment for the event and study procedure as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:33:16
User closed query 'PV Query: Please provide missing causality assessment for the event and study procedure as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 18:19:13
Query 'PV Query: Please provide missing causality assessment for the event and study procedure as soon as possible.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 20:59:32
User opened query 'PV Query: Please provide missing causality assessment for the event and study procedure as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:24:48
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:56:05
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	24 Nov 2020 17:11:26
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:56:08
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:56:10
User entered '0'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

Concomitant Medication

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 22:29:45
User closed query 'Per DM CLR re-query: Response noted. Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication and Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add conmed and conmed procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 06:15:39
Query 'Per DM CLR re-query: Response noted. Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication and Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add conmed and conmed procedure as appropriate or update action taken.' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 21:46:25
User opened query 'Per DM CLR re-query: Response noted. Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication and Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add conmed and conmed procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:33:20
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of COPD. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:32:56

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of COPD. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' answered with 'pending' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 22:26:05
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of COPD. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4)	08 Jan 2021 06:09:11
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: RQ: Response noted. Please update once records are available.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:32:54
Query 'Per DM CLR: RQ: Response noted. Please update once records are available.' answered with 'pending' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 22:26:18
User opened query 'Per DM CLR: RQ: Response noted. Please update once records are available.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 15:07:28
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 15:07:28
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Upon medical records are received.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 20:58:42
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:53:37
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:56:18
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 18:05:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	24 Nov 2020 17:11:45
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:35:50
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 18:19:19
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 20:58:56
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:25:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:56:20
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 22:29:25
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:43:45
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:43:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:43:39
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:43:36
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 22:27:18
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 22:27:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:26:48
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:26:35
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:37:52
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:37:04
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:36:50
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:31:12
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 18:19:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 18:19:30
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 18:19:27
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 18:19:23
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	28 Oct 2020 20:59:24
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	28 Oct 2020 20:59:20
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	28 Oct 2020 20:59:16
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4)	28 Oct 2020 20:59:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:26:23
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:25:46
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:25:40
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 20:24:36
User entered 'SPOKE WITH SUBJECT BY PHONE Mariete Rendon FOR DAY 50 SAFETY CALL. SHE WENT TO THE EMERGENCY ROOM PER INVESTIGATOR INSTRUCTIONS AND WAS ADMITTED ON 10OCT2020. NO INFORMATION AVAILABLE. STILL IN HOUSE. WILL REQUEST MEDICAL RECORDS WHEN DISCHARGED FOR DETAILS.' reason for change: Data Entry Error	(b) (4) (b) (4)	15 Oct 2020 14:37:50
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Oct 2020 14:37:28
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	15 Oct 2020 14:37:28

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Spoke with subject by phone for Day 50 safety call. She went to the emergency room per investigator instructions and was admitted on 10OCT2020. No information available. Still in house. Will request medical records when discharged for details.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	15 Oct 2020 14:37:28
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Oct 2020 14:34:48
User entered empty.	Mariete Rendon (b) (4)	15 Oct 2020 14:34:48

US3172322

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 17:11:26
User entered '0'	System	15 Oct 2020 14:34:48

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:35:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User closed query 'Per DM CLR: Per Diary Dose 2 Day 3-6, Pain at Injection Site/Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 23:14:06
Query 'Per DM CLR: Per Diary Dose 2 Day 3-6, Pain at Injection Site/Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Concomitant medication is recorded in medication log.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	28 Jan 2021 19:51:32
User opened query 'Per DM CLR: Per Diary Dose 2 Day 3-6, Pain at Injection Site/Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 11:15:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:04:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Sep 2020 20:59:37

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:06:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:06:53
Data point term sent to Coder User entered 'IBUPROFEN'	System Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:15 29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	29 Sep 2020 13:05:53
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:25:48
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'Related to the AE of acute exacerbation of COPD. ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	06 Nov 2020 20:46:05
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:28:10
User entered 'HEADACHE/FEVER'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '800'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'EVERY 6 HOURS'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	29 Sep 2020 13:05:53
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '25 Sep 2020'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	15 Oct 2020 18:47:26
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	29 Sep 2020 13:05:53
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '28 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	15 Oct 2020 18:47:26
User entered empty.	Jessie Downs (b) (4)	29 Sep 2020 13:05:53
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User entered empty.	System	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User entered empty.	System	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:26:27
User entered empty.	System	29 Sep 2020 13:05:53

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 13:07:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 13:07:51
	(b) (4)	
Data point term sent to Coder	System	29 Sep 2020 13:07:16
User entered 'TYLENOL'	Jessie Downs (b) (4)	29 Sep 2020 13:06:46
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE/FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE/FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:16:55
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE/FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE/FEVER did not meet the AE reporting criteria. ' answered with 'This was for a SARs not an AE.' (Site from DM).	Jessie Downs (b) (4)	18 Dec 2020 16:39:13
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE/FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE/FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:37:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:23:54
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'Related to acute exacerbation of COPD. ' (Site from DM).	Jessie Downs (b) (4)	06 Nov 2020 20:46:24
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:29:10
User entered 'HEADACHE/FEVER'	Jessie Downs (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '500'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'EVERY 6 HOURS'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: The Con Med start date is prior to the start date of eDiary event. Please review and reconcile all pages as appropriate. Update eCRFs.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:26:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Query 'Per DM CLR: The Con Med start date is prior to the start date of eDiary event. Please review and reconcile all pages as appropriate. Update eCRFs.' answered with 'Subject came in for a convalescent visit and reported taking over the counter Tylenol medication for headache/fever.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	28 Jan 2021 19:50:37
User opened query 'Per DM CLR: The Con Med start date is prior to the start date of eDiary event. Please review and reconcile all pages as appropriate. Update eCRFs.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 16:58:46
User entered '25 Sep 2020'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	24 Nov 2020 17:15:59
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	29 Sep 2020 13:06:46
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '12 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	24 Nov 2020 17:15:59
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	29 Sep 2020 13:06:46
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	24 Nov 2020 17:15:59
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 13:06:46

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:02:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:02:34
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 14:45:46
User entered 'Albuterol'	Mariete Rendon (b) (4)	15 Oct 2020 14:45:35
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Chronic obstructive pulmonary disease'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '90'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'ug (ug)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'other (OTHER)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'every 6 hours'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'un UNK 2010'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 14:45:35

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 17:37:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 17:37:06
Data point term sent to Coder	System	20 Jan 2021 17:36:18
User entered 'metformin'	Jessie Downs (b) (4)	20 Jan 2021 17:35:54
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'diabetes type ii'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '500'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'un UNK 2019'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 17:35:54

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(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)	20 Jan 2021 17:38:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 17:38:05
	(b) (4)	
Data point term sent to Coder	System	20 Jan 2021 17:37:18
User entered 'lisinopril'	Jessie Downs (b) (4)	20 Jan 2021 17:36:43
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'hypertension'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '10'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION (UNJAN2020). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 17:34:49
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION (UNJAN2020). Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'Data updated ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 16:48:06
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION (UNJAN2020). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:25:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '16 Dec 2019'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 17:36:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

Name of Medication

Audit	User	Time (GMT)
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)	03 May 2021 18:13:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:13:21
Data point term sent to Coder	System	03 May 2021 18:09:47
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	03 May 2021 18:08:50
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	03 May 2021 18:08:50
User entered 'BUDESONIDE FORMOTEROL (Symbicort) 160/4.5 mcg' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	03 May 2021 18:08:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 20:22:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 20:22:23
Data point term sent to Coder	System	20 Jan 2021 17:39:28
User entered 'budesonide formoterol'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'Chronic obstructive pulmonary disease'	Jessie Downs (b) (4)	20 Jan 2021 17:38:43
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '1'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'puff (PUFF)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jessie Downs (b) (4)	20 Jan 2021 17:38:43
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '16 Dec 2019'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 17:38:43

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(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)	20 Jan 2021 17:41:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 17:41:05
	(b) (4)	
Data point term sent to Coder	System	20 Jan 2021 17:40:29
User entered 'gabapentin'	Jessie Downs (b) (4)	20 Jan 2021 17:40:04
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Diabetic peripheral neuropathy'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '300'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	20 Jan 2021 17:40:04
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '16 Dec 2019'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 17:40:04

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 17:42:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 17:42:05
	(b) (4)	
Data point term sent to Coder	System	20 Jan 2021 17:41:32
User entered 'hydrochlorothiazide'	Jessie Downs (b) (4)	20 Jan 2021 17:40:55
	(b) (4)	

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'hypertension'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '25'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION (UNJAN2020). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 17:35:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION (UNJAN2020). Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'Data updated ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 16:47:21
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION (UNJAN2020). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:25:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '16 Dec 2019'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 17:40:55

US3172322

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:35:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User closed query 'Per ETRTR: SAE "Worsening of Chronic Obstructive Pulmonary Disease" indicates Concomitant procedure was done, please update accordingly, thanks.' (Site from CRA). Query 'Per ETRTR: SAE "Worsening of Chronic Obstructive Pulmonary Disease" indicates Concomitant procedure was done, please update accordingly, thanks.' answered with 'Pending to receive medical records.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 00:37:05
User opened query 'Per ETRTR: SAE "Worsening of Chronic Obstructive Pulmonary Disease" indicates Concomitant procedure was done, please update accordingly, thanks.' (Site from CRA).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 13:39:19
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:19:30
	Mariete Rendon (b) (4) (b) (4)	03 Sep 2020 19:38:21

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'USA-US118-2020-MRNA-1273-P301000004'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Mark'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Kutner'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'FL'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:19:43
User entered 'US'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Mar 2021 18:11:02
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '3'	System	25 Nov 2020 13:26:47
User entered '2'	System	29 Oct 2020 18:19:54
User entered '1'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'USA-US118-2020-MRNA-1273-P301000004'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Mark'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Kutner'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'FL'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:19:43
User entered 'US'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Mar 2021 18:11:02
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '3'	System	25 Nov 2020 13:26:47
User entered '2'	System	29 Oct 2020 18:19:54
User entered '1'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:35:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '15/Oct/2020 20:17'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:35:42

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)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:19:43
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'USA-US118-2020-MRNA-1273-P301000004'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Mark'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Kutner'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'FL'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:19:43
User entered 'US'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Mar 2021 18:11:02
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '3'	System	25 Nov 2020 13:26:47
User entered '2'	System	29 Oct 2020 18:19:54
User entered '1'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:35:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '29/Oct/2020 18:19'	System	29 Oct 2020 18:19:54

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:35:42

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)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:26:36
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 18:19:54

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'USA-US118-2020-MRNA-1273-P301000004'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Mark'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Kutner'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'FL'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:19:43
User entered 'US'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Mar 2021 18:11:02
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '3'	System	25 Nov 2020 13:26:47
User entered '2'	System	29 Oct 2020 18:19:54
User entered '1'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:35:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '25/Nov/2020 13:26'	System	25 Nov 2020 13:26:47

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:35:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:10:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 13:26:47

US3172322

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'USA-US118-2020-MRNA-1273-P301000004'	System	16 Oct 2020 00:17:31

US3172322

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Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

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Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

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Folder: SAE USA-US118-2020-MRNA-1273-P301000004

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:17:31

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'No (N)'	System	16 Oct 2020 00:17:31

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Mark'	System	16 Oct 2020 00:17:31

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Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'Kutner'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

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Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:29:38
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:17:45
User entered 'FL'	System	16 Oct 2020 00:17:31

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:19:43
User entered 'US'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Mar 2021 18:11:02
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:29:38
	(b) (4)	
User entered '3'	System	25 Nov 2020 13:26:47
User entered '2'	System	29 Oct 2020 18:19:54
User entered '1'	System	16 Oct 2020 00:17:49

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:35:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:58:50
	(b) (4)	
User entered '01/Mar/2021 13:11'	System	01 Mar 2021 18:11:02

US3172322

Folder: SAE USA-US118-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:35:42

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)	03 Mar 2021 13:58:50
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 18:11:02