

US3142137 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:25:34

All time stamps listed in this document are displayed in GMT

US3142137

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

[Participant ID](#)

US3142137

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

US3142137

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Apr 2021 20:15:23

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Date of Informed Consent (<i>dd MMM yyyy</i>)	6 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Apr 2021 20:15:23

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 20:15:23

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	CATARACTS, BILATERAL
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 (3)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	POSTNASAL DRIP
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	HEARTBURN
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 (8)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	OA IN BOTH KNEES
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Start Year (derived)	1972
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	JOINT PAIN - NOT SPECIFIED
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	NEUROPATHY IN HANDS AND FEET
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	ECZEMA - NOT SPECIFIED LOCATION
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	HIVES, UNSPECIFIED LOCATION
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	RASHES RELATED TO FOOD ALLERGIES, UNSPECIFIED LOCATION
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	SHINGLES
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Condition	MUSCULAR DEGENERATION
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: Vital Signs

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:33 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 14:33
Height (<i>xxx.x</i>)	72 in
Weight (<i>xxx.x</i>)	200 lb
BMI (<i>xxx.x</i>)	27.18159 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Date of assessment (dd MMM yyyy) 6 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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) 18 Apr 2021 20:15:23

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101737

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) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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)	6 AUG 2020
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 14:00
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 AUG 2020
Time of assessment (00:00-23:59)	14:54 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 14:54
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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) 6 AUG 2020

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

Treatment Date and Time (derived) 6 AUG 2020 14:24

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 AUG 2020
Collection time (00:00-23:59)	14:20 (24 HR)
Collection date and time (derived)	6 AUG 2020 14:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Collection date (dd MMM yyyy)			6 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:22	6 AUG 2020 14:22
Nasopharyngeal Swab 2	Yes	14:22	6 AUG 2020 14:22

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 02:41:29

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

96.5 °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

06 AUG 2020 15:08

PC Open Date & Time

06 AUG 2020 14:44

PC Close Date & Time

06 AUG 2020 17:14

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °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	07 AUG 2020 07:39
PC Open Date & Time	06 AUG 2020 18:09
PC Close Date & Time	07 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

95.9 °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

08 AUG 2020 07:17

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 10:17

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

09 AUG 2020 20:07

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

10 AUG 2020 22:37

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 19:15

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 18:12

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

06 AUG 2020 15:10

PC Open Date & Time

06 AUG 2020 14:44

PC Close Date & Time

06 AUG 2020 17:14

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

07 AUG 2020 07:40

PC Open Date & Time

06 AUG 2020 18:09

PC Close Date & Time

07 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

08 AUG 2020 07:17

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

09 AUG 2020 10:17

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

09 AUG 2020 20:08

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

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

10 AUG 2020 21:44

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 19:15

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 18:13

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 15:10
PC Open Date & Time	06 AUG 2020 14:44
PC Close Date & Time	06 AUG 2020 17:14

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 07:41
PC Open Date & Time	06 AUG 2020 18:09
PC Close Date & Time	07 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

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 ☒

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

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 ☒

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 10:18
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:08
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

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)

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 21:44
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

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 ☒

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 19:14
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 AUG 2020 21:52
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3142137

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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)	4 SEP 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 14:35
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	15:33 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:33
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	11 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3142137

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 15:03 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 15:03

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

US3142137

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	14:42 (24 HR)
Collection date and time (derived)	4 SEP 2020 14:42

US3142137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:38	4 SEP 2020 14:38
Nasopharyngeal Swab 2	Yes	14:38	4 SEP 2020 14:38

US3142137

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

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

04 SEP 2020 15:23

PC Close Date & Time

04 SEP 2020 17:53

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 SEP 2020 18:48

PC Close Date & Time

05 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 21:54

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

97.2 °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

06 SEP 2020 22:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 20:13

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 22:32

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 19:51

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 15:23

PC Close Date & Time

04 SEP 2020 17:53

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 18:48

PC Close Date & Time

05 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

05 SEP 2020 21:54

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

06 SEP 2020 22:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

07 SEP 2020 20:14

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

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

08 SEP 2020 22:33

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:51

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE. Please select one response below	None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/> No <input type="radio"/>
Please record - REDNESS AT INJECTION SITE (in mm) Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/> No <input type="radio"/>
Please record - SWELLING/HARDNESS AT INJECTION SITE (in mm) Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - UNDERARM GLAND SWELLING OR TENDERNESS. Please select one response below	None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 15:23

PC Close Date & Time

04 SEP 2020 17:53

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 18:48

PC Close Date & Time

05 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

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 ☒

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:55
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

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 ☒

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:24
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

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 ☒

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 20:14
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

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 ☒

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 22:33
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

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 ☒

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 19:52
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3142137

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	VISIT3

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 09:08
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142137

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3142137

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	09:17 (24 HR)
Collection date and time (derived)	30 SEP 2020 09:17

US3142137

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 OCT 2020 11:40:11
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

13 OCT 2020 08:48:38

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☒

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 OCT 2020 12:07:45

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 92

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

No ☒

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 17:29:02

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-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"/>

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 NOV 2020 07:19:11
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 10:47:56

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

28 NOV 2020 08:17:04

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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	05 DEC 2020 07:27:31
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 09:55:27

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 09:13:31

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 08:52:42

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 07:20:38

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 07:32:31

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 08:17:13

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 08:10:15
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 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	06 FEB 2021 21:26:41
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	13 FEB 2021 07:40:21
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 07:32:16

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 07:43:57

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

09 MAR 2021 12:46:39

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

13 MAR 2021 08:33:49

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

20 MAR 2021 07:36:00

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

27 MAR 2021 01:39:17

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

03 APR 2021 07:34:29

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

10 APR 2021 07:28:21

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 08:27:45

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 07:34:15

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 06:24:55

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 418

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

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

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

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

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

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

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

Patient Cloud Open Date & Time	23 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐ 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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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°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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐ 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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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="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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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="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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

Patient Cloud Open Date & Time	05 FEB 2022 00:01
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Patient Cloud Close Date & Time	09 FEB 2022 23:59
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US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 <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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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°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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐ 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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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 ☐

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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"/>

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3142137

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:25:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 07:44:17

US3142137

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 NOV 2020

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

Comments SUBJECT STOPPED TAKING
HCTV MEDICATION ON
If Contact Not Made, please provide Comments 05NOV2020

US3142137

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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) _____

US3142137

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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.

US3142137

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 FEB 2021

Collection time (00:00-23:59)

09:06 (24 HR)

Collection date and time (derived)

16 FEB 2021 09:06

US3142137

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142137

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:25:34

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3142137

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

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

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

Visit date (dd MMM yyyy)	18 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3142137

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

Form: Unblinding

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Date of updated informed consent (<i>dd MMM yyyy</i>)	18 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	18 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3142137

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

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

US3142137

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	15:37 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 15:37
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3142137

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	16:32 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 16:32
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3142137

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

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3142137

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

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 18 JAN 2021

What was the treatment time? (00:00-23:59) 16:02 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 16:02

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

US3142137

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00-23:59)	14:53 (24 HR)
Collection date and time (derived)	18 JAN 2021 14:53

US3142137

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	14:58
Collection Date and Time (derived)	18 JAN 2021 14:58

US3142137

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

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 JAN 2021

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

Comments
If Contact Not Made, please provide Comments WHOLE ARM HURT FOR 2 DAYS
FOLLOWING VACCINE STILL
SWELLED FOR 2 DAYS. PAIN
ONLY WHEN TOUCHED.

US3142137

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	9:43 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 9:43
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 11:19
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3142137

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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

US3142137

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 16 FEB 2021

What was the treatment time? (00:00-23:59) 10:49 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 10:49

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

US3142137

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

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

If Contact Not Made, please provide Comments

US3142137

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:15:23

Generated On: 09 Jun 2021 15:25:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142137

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 APR 2021
Time of assessment (<i>00:00-23:59</i>)	09:28 (24 HR)
Vital Signs Date and Time (derived)	1 APR 2021 09:28
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142137

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 APR 2021

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

US3142137

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:15:02

Generated On: 09 Jun 2021 15:25:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 APR 2021
Collection time (00:00-23:59)	10:11 (24 HR)
Collection date and time (derived)	1 APR 2021 10:11

US3142137

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Apr 2021 02:41:29

Generated On: 09 Jun 2021 15:25:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

AEID	USA-US064-2021-MRNA-1273-P30 1000009
Adverse event	LEFT KIDNEY CARCINOMA
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)	09 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	04 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	07 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

SUBJECT WAS BEING FOLLOWED MEDICALLY AFTER A CAR ACCIDENT 25 JULY 2020. DURING THE COURSE OF FOLLOW UP FOR A PRESTUDY ISSUE OF BACK PAIN RELATED TO THE CAR ACCIDENT, AN MRI DONE 09 FEB 2021 FOUND A LEFT KIDNEY TUMOR SUSPICIOUS FOR KIDNEY CARCINOMA. SUBJECT WAS SCHEDULED FOR A LEFT RADICAL NEPHRECTOMY ON 04 MAR 2021. SUBJECT HOSPITALIZED FOR A LEFT RADICAL NEPHRECTOMY ON 04 MARCH 2021 AND DISCHARGED HOME 07 MARCH 2021. SUBJECT'S LEFT KIDNEY WAS REMOVED 04 MARCH 2021 AND PER SUBJECT THE MARGINS WERE "CLEAN" AND THE CANCER WAS COMPLETELY REMOVED. NO RADIATION OR CHEMOTHERAPY IS PLANNED. SUBJECT WILL BE FOLLOWED BY PCP WITH A CHEST X-RAY AND MRI OR CT SCAN EVERY 6 MONTHS. SUBJECT'S HOSPITALIZATION RECORDS WILL BE REQUESTED.

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

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Apr 2021 02:41:29

Generated On: 09 Jun 2021 15:25:34

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

Yes ☒

No ☐

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

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Name of Medication ARMOUR THYROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1992
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1985
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Name of Medication HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	5 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		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) 25 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3142137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3142137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 18 Apr 2021 20:15:01

Generated On: 09 Jun 2021 15:25:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 MAR 2021	LEFT RADICAL KIDNEY NEPHRECTOMY	Adverse Event	

US3142137

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:25:34

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

US3142137

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:25:34

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 ☐

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Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

SAEID	USA-US064-2021-MRNA-1273-P301000009
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	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Apr 2021 20:15:22

Generated On: 09 Jun 2021 15:25:34

SAEID	USA-US064-2021-MRNA-1273-P301000009
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	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	02/APR/2021 09:22
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

US3142137 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142137

Form: Participant Creation

Generated On: 09 Jun 2021 15:25:34

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:23:11
User entered 'US3142137'	RWS_ENDPOINT	06 Aug 2020 19:19:26
	ENDPOINT (b) (4)	

US3142137

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:25:10
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 20:49:21

US3142137

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:25:10
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:19:27

US3142137

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:25:10
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	06 Aug 2020 20:49:21

US3142137

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'SCRN'	System	06 Aug 2020 20:49:21

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4)	16 Oct 2020 15:28:46
User entered '(b) (6)1959'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:19:28

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered '60'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'YEARS'	System	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '60'	System	06 Aug 2020 20:49:38

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered 'Female (F)'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered 'l'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered '0'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered '0'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered '0'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered '0'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered '0'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered empty.	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered '0'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:25:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:28:50
User entered '0'	Meghan York (b) (4)	06 Aug 2020 21:58:39

US3142137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:25:34

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:29:21
User entered '6 Aug 2020'	Meghan York (b) (4)	06 Aug 2020 20:49:38

US3142137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Aug 2020'	System	06 Aug 2020 20:49:38

US3142137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2020'	System	06 Aug 2020 20:49:38

US3142137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:25:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:23:30
DataPoint Un-verified.	Meghan York (b) (4)	09 Dec 2020 23:18:26
	(b) (4)	
User entered 'Amendment 2 (2)' reason for change:	Meghan York (b) (4)	09 Dec 2020 23:18:26
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:29:21
User entered 'Amendment 1 (1)'	Meghan York (b) (4)	06 Aug 2020 20:49:38
	(b) (4)	

US3142137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:29:21
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 20:49:38

US3142137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:25:34

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:29:21
User entered empty.	Meghan York (b) (4)	06 Aug 2020 20:49:38

US3142137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:25:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:29:21
User entered empty.	Meghan York (b) (4)	06 Aug 2020 20:49:38

US3142137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:25:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:29:21
User entered 'No (N)'	Meghan York (b) (4)	06 Aug 2020 20:49:38

US3142137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:25:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4)	16 Oct 2020 15:29:21
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:19:27

US3142137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:25:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'I'	System	06 Aug 2020 20:49:42

US3142137

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:29:33
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 20:49:42

US3142137

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:25:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:30:38
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 21:58:45

US3142137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4)	22 Oct 2020 03:11:35
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 03:11:31
DataPoint Verified.		22 Oct 2020 03:11:26
User closed query 'Please verify if Macular Degeneration should be added to the medical history as per source.' (Site from CRA).		22 Oct 2020 03:11:21
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 17:19:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	19 Oct 2020 17:19:11
Query 'Please verify if Macular Degeneration should be added to the medical history as per source.' answered with 'added ' (Site from CRA).	Meghan York (b) (4)	19 Oct 2020 17:07:40
Data point term sent to Coder	System	19 Oct 2020 17:00:16
DataPoint Un-verified.	Meghan York (b) (4)	19 Oct 2020 16:59:19
Coding entries removed.	(b) (4)	19 Oct 2020 16:59:19
User entered 'NEARSIGHTED, Bilateral' reason for change: Data Entry Error	Meghan York (b) (4)	19 Oct 2020 16:59:19
User opened query 'Please verify if Macular Degeneration should be added to the medical history as per source.' (Site from CRA).	(b) (4)	16 Oct 2020 15:40:39
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 22:01:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	06 Aug 2020 22:01:04
Data point term sent to Coder	System	06 Aug 2020 22:00:23
User entered 'nearsighted'	Meghan York (b) (4)	06 Aug 2020 21:59:35

US3142137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2000'	Meghan York (b) (4)	06 Aug 2020 21:59:35

US3142137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	06 Aug 2020 21:59:35

US3142137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 21:59:35

US3142137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	06 Aug 2020 21:59:35

US3142137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	06 Aug 2020 21:59:35

US3142137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2000'	System	06 Aug 2020 21:59:35

US3142137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2000'	System	06 Aug 2020 21:59:35

US3142137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	06 Aug 2020 21:59:35

US3142137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	06 Aug 2020 21:59:35

US3142137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User closed query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).		16 Oct 2020 14:03:29
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:14:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:14:53
Query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' answered with 'term updated' (Site from DM).	Jami Wagner (b) (4)	13 Oct 2020 20:13:26
Data point term sent to Coder	System	13 Oct 2020 20:13:18
Coding entries removed.	Jami Wagner (b) (4)	13 Oct 2020 20:13:15
User entered 'CATARACTS, bilateral' reason for change: Data Entry Error	Jami Wagner (b) (4)	13 Oct 2020 20:13:15
User opened query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:10:37
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:01:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:01:05
Data point term sent to Coder	System	06 Aug 2020 22:00:26
User entered 'cataracts'	Meghan York (b) (4)	06 Aug 2020 22:00:11

US3142137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2019'	Meghan York (b) (4)	06 Aug 2020 22:00:11

US3142137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	06 Aug 2020 22:00:11

US3142137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 22:00:11

US3142137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	06 Aug 2020 22:00:11

US3142137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	06 Aug 2020 22:00:11

US3142137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2019'	System	06 Aug 2020 22:00:11

US3142137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:25:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2019'	System	06 Aug 2020 22:00:11

US3142137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	06 Aug 2020 22:00:11

US3142137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	06 Aug 2020 22:00:11

US3142137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:25:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:31:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Upper-airway cough syndrome, LLT: Postnasal drip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 22:03:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 22:03:07
Data point term sent to Coder	System	06 Aug 2020 22:01:28
User entered 'postnasal drip'	Meghan York (b) (4) (b) (4)	06 Aug 2020 22:00:54

US3142137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 1965'	Meghan York (b) (4)	06 Aug 2020 22:00:54

US3142137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	06 Aug 2020 22:00:54

US3142137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 22:00:54

US3142137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	06 Aug 2020 22:00:54

US3142137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	06 Aug 2020 22:00:54

US3142137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1965'	System	06 Aug 2020 22:00:54

US3142137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1965'	System	06 Aug 2020 22:00:54

US3142137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	06 Aug 2020 22:00:54

US3142137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	06 Aug 2020 22:00:54

US3142137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:25:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:03:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:03:08
Data point term sent to Coder	System	06 Aug 2020 22:02:29
User entered 'seasonal allergies'	Meghan York (b) (4)	06 Aug 2020 22:01:32

US3142137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 1965'	Meghan York (b) (4)	06 Aug 2020 22:01:32

US3142137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	06 Aug 2020 22:01:32

US3142137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 22:01:32

US3142137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:25:34

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	06 Aug 2020 22:01:32

US3142137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	06 Aug 2020 22:01:32

US3142137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1965'	System	06 Aug 2020 22:01:32

US3142137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1965'	System	06 Aug 2020 22:01:32

US3142137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	06 Aug 2020 22:01:32

US3142137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	06 Aug 2020 22:01:32

US3142137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
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)	06 Aug 2020 22:03:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:03:07
Data point term sent to Coder	System	06 Aug 2020 22:02:29
User entered 'tonsillitis'	Meghan York (b) (4)	06 Aug 2020 22:02:11

US3142137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:25:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		06 Aug 2020 22:29:49
User entered 'UN UNK 1960' reason for change:	Meghan York (b) (4)	06 Aug 2020 22:29:49
Data Entry Error	(b) (4)	
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	06 Aug 2020 22:02:11
User entered 'UN UNK 1959'	Meghan York (b) (4)	06 Aug 2020 22:02:11
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	06 Aug 2020 22:02:11

US3142137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'No (N)'	Meghan York (b) (4)	06 Aug 2020 22:02:11

US3142137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:25:34

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2005'	Meghan York (b) (4)	06 Aug 2020 22:02:11

US3142137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	06 Aug 2020 22:02:11

US3142137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1960'	System	06 Aug 2020 22:29:49
User entered 'Jan 1959'	System	06 Aug 2020 22:02:11

US3142137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1960'	System	06 Aug 2020 22:29:49
User entered '1959'	System	06 Aug 2020 22:02:11

US3142137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2005'	System	06 Aug 2020 22:02:11

US3142137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2005'	System	06 Aug 2020 22:02:11

US3142137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:25:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:31:46
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.' (Site from DM).		16 Oct 2020 14:03:38
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.' answered with 'no con meds are taken for this condition' (Site from DM).	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 20:14:24
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:11:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:41:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:41:15
Data point term sent to Coder	System	07 Aug 2020 14:40:07
User entered 'asthma'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:39:55

US3142137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 1990'	Meghan York (b) (4)	07 Aug 2020 14:39:55

US3142137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:39:55

US3142137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:39:55

US3142137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:39:55

US3142137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:39:55

US3142137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1990'	System	07 Aug 2020 14:39:55

US3142137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1990'	System	07 Aug 2020 14:39:55

US3142137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:39:55

US3142137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:39:55

US3142137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:44:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:44:18
Data point term sent to Coder	System	07 Aug 2020 14:43:12
User entered 'heartburn'	Meghan York (b) (4)	07 Aug 2020 14:42:30

US3142137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2015'	Meghan York (b) (4)	07 Aug 2020 14:42:30

US3142137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:42:30

US3142137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:42:30

US3142137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:42:30

US3142137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:42:30

US3142137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2015'	System	07 Aug 2020 14:42:30

US3142137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2015'	System	07 Aug 2020 14:42:30

US3142137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:42:30

US3142137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:42:30

US3142137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:08:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:08:58
Data point term sent to Coder	System	07 Aug 2020 14:43:13
User entered 'OA in both knees'	Meghan York (b) (4)	07 Aug 2020 14:43:02

US3142137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 1972'	Meghan York (b) (4)	07 Aug 2020 14:43:02

US3142137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:43:02

US3142137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:43:02

US3142137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:25:34

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:43:02

US3142137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:43:02

US3142137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1972'	System	07 Aug 2020 14:43:02

US3142137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1972'	System	07 Aug 2020 14:43:02

US3142137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:43:02

US3142137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:43:02

US3142137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User closed query 'Per DM CLR: Please specify the location of Joint Pain. Update Med History eCRF as appropriate. ' (Site from DM).		15 Oct 2020 04:02:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 23:06:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 23:06:23
Data point term sent to Coder	System	13 Oct 2020 18:54:50
Query 'Per DM CLR: Please specify the location of Joint Pain. Update Med History eCRF as appropriate. ' answered with 'done' (Site from DM).	Jill York (b) (4)	13 Oct 2020 18:54:17
Coding entries removed.	Jill York (b) (4)	13 Oct 2020 18:54:04
User entered 'JOINT PAIN - not specified' reason for change: Data Entry Error	Jill York (b) (4)	13 Oct 2020 18:54:04
User opened query 'Per DM CLR: Please specify the location of Joint Pain. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:11:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 14:45:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 14:45:18
Data point term sent to Coder	System	07 Aug 2020 14:44:13
User entered 'joint pain'	Meghan York (b) (4)	07 Aug 2020 14:43:40

US3142137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2000'	Meghan York (b) (4)	07 Aug 2020 14:43:40

US3142137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:43:40

US3142137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:43:40

US3142137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:43:40

US3142137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:43:40

US3142137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2000'	System	07 Aug 2020 14:43:40

US3142137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2000'	System	07 Aug 2020 14:43:40

US3142137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:43:40

US3142137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:43:40

US3142137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:31:46
User coded data point as SOC: Nervous system disorders, HLG: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:32:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:32:16
Data point term sent to Coder	System	07 Aug 2020 14:45:14
User entered 'Neuropathy in hands and feet'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:44:27

US3142137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:25:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		07 Aug 2020 14:44:49
User entered 'UN UNK 1960' reason for change:	Meghan York (b) (4)	07 Aug 2020 14:44:49
Data Entry Error	(b) (4)	
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	07 Aug 2020 14:44:27
User entered 'UN UNK 1959'	Meghan York (b) (4)	07 Aug 2020 14:44:27
	(b) (4)	

US3142137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:44:27

US3142137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:44:27

US3142137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:25:34

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:44:27

US3142137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:44:27

US3142137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1960'	System	07 Aug 2020 14:44:49
User entered 'Jan 1959'	System	07 Aug 2020 14:44:27

US3142137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1960'	System	07 Aug 2020 14:44:49
User entered '1959'	System	07 Aug 2020 14:44:27

US3142137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:44:27

US3142137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:44:27

US3142137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:31:46
User closed query 'Per DM CLR: Please specify the location of Eczema. Update Med History eCRF as appropriate. ' (Site from DM).		15 Oct 2020 04:03:07
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:34:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:34:23
Query 'Per DM CLR: Please specify the location of Eczema. Update Med History eCRF as appropriate. ' answered with 'done' (Site from DM).	Jill York (b) (4)	13 Oct 2020 18:55:56
Data point term sent to Coder	System	13 Oct 2020 18:55:52
Coding entries removed.	Jill York (b) (4)	13 Oct 2020 18:55:46
User entered 'ECZEMA - not specified location' reason for change: Data Entry Error	Jill York (b) (4)	13 Oct 2020 18:55:46
User opened query 'Per DM CLR: Please specify the location of Eczema. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:23:01
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:47:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:47:16
Data point term sent to Coder	System	07 Aug 2020 14:46:16
User entered 'Eczema'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:45:29

US3142137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 1960'	Meghan York (b) (4)	07 Aug 2020 14:45:29

US3142137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:25:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:45:29

US3142137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:45:29

US3142137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:45:29

US3142137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:45:29

US3142137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1960'	System	07 Aug 2020 14:45:29

US3142137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1960'	System	07 Aug 2020 14:45:29

US3142137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:45:29

US3142137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:45:29

US3142137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:25:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4)	16 Oct 2020 15:31:46
User closed query 'Per DM CLR: Please specify the location of Hives. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:03:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 08:27:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	14 Oct 2020 08:27:26
Data point term sent to Coder	System	13 Oct 2020 20:10:10
Query 'Per DM CLR: Please specify the location of Hives. Update Med History eCRF as appropriate. ' answered with 'updated term' (Site from DM).	Jami Wagner (b) (4)	13 Oct 2020 20:09:32
Coding entries removed.	(b) (4)	
	Jami Wagner (b) (4)	13 Oct 2020 20:09:13
User entered 'HIVES, unspecified location' reason for change: Data Entry Error	Jami Wagner (b) (4)	13 Oct 2020 20:09:13
User opened query 'Per DM CLR: Please specify the location of Hives. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	02 Sep 2020 06:23:34
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:47:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	07 Aug 2020 14:47:15
Data point term sent to Coder	System	07 Aug 2020 14:46:14
User entered 'hives'	Meghan York (b) (4)	07 Aug 2020 14:46:10
	(b) (4)	

US3142137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 1960'	Meghan York (b) (4)	07 Aug 2020 14:46:10

US3142137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:46:10

US3142137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:46:10

US3142137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:46:10

US3142137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:46:10

US3142137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1960'	System	07 Aug 2020 14:46:10

US3142137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1960'	System	07 Aug 2020 14:46:10

US3142137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:46:10

US3142137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:46:10

US3142137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis allergic, LLT: Allergic rash - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 18:25:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 18:25:42
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User closed query 'Per DM CLR: Please specify the location of Rashes. Update Med History eCRF as appropriate. ' (Site from DM).		16 Oct 2020 14:04:03
Query 'Per DM CLR: Please specify the location of Rashes. Update Med History eCRF as appropriate. ' answered with 'term updated' (Site from DM).	Jami Wagner (b) (4)	13 Oct 2020 20:10:16
Data point term sent to Coder	System	13 Oct 2020 20:10:10
User entered 'RASHES RELATED TO FOOD ALLERGIES, unspecified location' reason for change: Data Entry Error	Jami Wagner (b) (4)	13 Oct 2020 20:10:08
User opened query 'Per DM CLR: Please specify the location of Rashes. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:23:49
Data point term sent to Coder	System	07 Aug 2020 14:47:18
User entered 'rashes related to food allergies'	Meghan York (b) (4)	07 Aug 2020 14:46:55

US3142137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 1960'	Meghan York (b) (4)	07 Aug 2020 14:46:55

US3142137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:46:55

US3142137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:46:55

US3142137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:25:34

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:46:55

US3142137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:46:55

US3142137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1960'	System	07 Aug 2020 14:46:55

US3142137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1960'	System	07 Aug 2020 14:46:55

US3142137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:46:55

US3142137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:46:55

US3142137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:25:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:31:46
User closed query 'Per DM CLR: Please review this condition and verify if the subject is Surgically Sterile. Please review Childbearing Potential eCRF page, as this information is noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).		15 Oct 2020 04:03:14
Query 'Per DM CLR: Please review this condition and verify if the subject is Surgically Sterile. Please review Childbearing Potential eCRF page, as this information is noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' answered with 'done' (Site from DM).	Jill York (b) (4)	13 Oct 2020 18:58:03
User opened query 'Per DM CLR: Please review this condition and verify if the subject is Surgically Sterile. Please review Childbearing Potential eCRF page, as this information is noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:24:03
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:49:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:49:09
Data point term sent to Coder	System	07 Aug 2020 14:48:18
User entered 'post menopausal'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:47:23

US3142137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2009'	Meghan York (b) (4)	07 Aug 2020 14:47:23

US3142137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:47:23

US3142137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:47:23

US3142137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:25:34

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:47:23

US3142137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:47:23

US3142137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2009'	System	07 Aug 2020 14:47:23

US3142137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:25:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2009'	System	07 Aug 2020 14:47:23

US3142137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:47:23

US3142137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:47:23

US3142137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
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.' (Site from DM).		16 Oct 2020 14:04:35
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)	13 Oct 2020 20:13:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	13 Oct 2020 20:13:25
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.' answered with 'Term updated to match term used on con med page' (Site from DM).	Jami Wagner (b) (4)	13 Oct 2020 20:12:19
Data point term sent to Coder	System	13 Oct 2020 20:12:12
Coding entries removed.	Jami Wagner (b) (4)	13 Oct 2020 20:12:12
User entered 'Hypertension' reason for change: Data Entry Error	Jami Wagner (b) (4)	13 Oct 2020 20:12:12
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.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:29:38
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 14:49:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 14:49:09

US3142137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	07 Aug 2020 14:48:21
User entered 'high blood pressure'	Meghan York (b) (4)	07 Aug 2020 14:47:58
	(b) (4)	

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Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2007'	Meghan York (b) (4)	07 Aug 2020 14:47:58

US3142137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:47:58

US3142137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:47:58

US3142137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:47:58

US3142137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:47:58

US3142137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2007'	System	07 Aug 2020 14:47:58

US3142137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2007'	System	07 Aug 2020 14:47:58

US3142137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:47:58

US3142137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:47:58

US3142137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:25:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:50:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:50:16
Data point term sent to Coder	System	07 Aug 2020 14:49:23
User entered 'depression'	Meghan York (b) (4)	07 Aug 2020 14:48:50

US3142137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2009'	Meghan York (b) (4)	07 Aug 2020 14:48:50

US3142137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:48:50

US3142137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:48:50

US3142137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2010'	Meghan York (b) (4)	07 Aug 2020 14:48:50

US3142137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:48:50

US3142137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2009'	System	07 Aug 2020 14:48:50

US3142137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2009'	System	07 Aug 2020 14:48:50

US3142137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2010'	System	07 Aug 2020 14:48:50

US3142137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2010'	System	07 Aug 2020 14:48:50

US3142137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:25:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:51:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:51:18
Data point term sent to Coder	System	07 Aug 2020 14:50:24
User entered 'shingles'	Meghan York (b) (4)	07 Aug 2020 14:49:40

US3142137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2013'	Meghan York (b) (4)	07 Aug 2020 14:49:40

US3142137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:49:40

US3142137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:49:40

US3142137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2017'	Meghan York (b) (4)	07 Aug 2020 14:49:40

US3142137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:49:40

US3142137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2013'	System	07 Aug 2020 14:49:40

US3142137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2013'	System	07 Aug 2020 14:49:40

US3142137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2017'	System	07 Aug 2020 14:49:40

US3142137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2017'	System	07 Aug 2020 14:49:40

US3142137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:25:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:31:46
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female malignant and unspecified, HLT: Uterine neoplasms malignant NEC, PT: Uterine cancer, LLT: Uterine cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:51:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:51:17
Data point term sent to Coder	System	07 Aug 2020 14:50:25
User entered 'uterine cancer'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:50:16

US3142137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'UN UNK 2009'	Meghan York (b) (4)	07 Aug 2020 14:50:16

US3142137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:50:16

US3142137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:50:16

US3142137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:25:30
User closed query 'Per DM CLR: Please note that stop date is unexpected for chronic condition, if patient underwent the surgery for reported condition, then please add procedure details to MH eCRF' (Site from DM).		23 Oct 2020 07:47:35
DataPoint Un-verified.		16 Oct 2020 15:37:51
DataPoint Verified.		16 Oct 2020 15:31:46
Query 'Per DM CLR: Please note that stop date is unexpected for chronic condition, if patient underwent the surgery for reported condition, then please add procedure details to MH eCRF' answered with 'no end date' (Site from DM).	Jill York (b) (4)	13 Oct 2020 18:56:34
User opened query 'Per DM CLR: Please note that stop date is unexpected for chronic condition, if patient underwent the surgery for reported condition, then please add procedure details to MH eCRF' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:43:54
User entered 'UN UNK 2009'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:50:16

US3142137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:50:16

US3142137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2009'	System	07 Aug 2020 14:50:16

US3142137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:25:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2009'	System	07 Aug 2020 14:50:16

US3142137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2009'	System	07 Aug 2020 14:50:16

US3142137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2009'	System	07 Aug 2020 14:50:16

US3142137

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:25:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:31:46
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:38:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:38:34
Data point term sent to Coder	System	14 Oct 2020 15:35:21
User entered 'HYPOTHYROIDISM'	Meghan York (b) (4) (b) (4)	14 Oct 2020 15:34:36

US3142137

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'un UNK 1992'	Meghan York (b) (4)	14 Oct 2020 15:34:36

US3142137

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	14 Oct 2020 15:34:36

US3142137

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered 'Yes (Y)'	Meghan York (b) (4)	14 Oct 2020 15:34:36

US3142137

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:25:34

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered empty.	Meghan York (b) (4)	14 Oct 2020 15:34:36

US3142137

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:31:46
User entered '0'	Meghan York (b) (4)	14 Oct 2020 15:34:36

US3142137

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1992'	System	14 Oct 2020 15:34:36

US3142137

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1992'	System	14 Oct 2020 15:34:36

US3142137

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	14 Oct 2020 15:34:36

US3142137

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	14 Oct 2020 15:34:36

US3142137

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:25:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:26:07
User closed query 'Per DM CLR: Please specify the location of MUSCULAR DEGENERATION. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		29 Oct 2020 13:37:13
Query 'Per DM CLR: Please specify the location of MUSCULAR DEGENERATION. 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 'location was not specified ' (Site from DM).	Meghan York (b) (4) (b) (4)	27 Oct 2020 19:38:16
User opened query 'Per DM CLR: Please specify the location of MUSCULAR DEGENERATION. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:52:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle atrophy, LLT: Muscle degeneration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 17:19:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 17:19:18
Data point term sent to Coder	System	19 Oct 2020 17:08:35
User entered 'muscular degeneration'	Meghan York (b) (4) (b) (4)	19 Oct 2020 17:08:26

US3142137

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:26:08
User entered 'un UNK 2019'	Meghan York (b) (4)	19 Oct 2020 17:08:26

US3142137

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:26:10
User entered '0'	Meghan York (b) (4)	19 Oct 2020 17:08:26

US3142137

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:25:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:26:12
User entered 'Yes (Y)'	Meghan York (b) (4)	19 Oct 2020 17:08:26

US3142137

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:25:34

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:26:14
User entered empty.	Meghan York (b) (4) (b) (4)	19 Oct 2020 17:08:26

US3142137

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:25:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:26:16
User entered '0'	Meghan York (b) (4)	19 Oct 2020 17:08:26

US3142137

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:25:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2019'	System	19 Oct 2020 17:08:26

US3142137

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:25:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2019'	System	19 Oct 2020 17:08:26

US3142137

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	19 Oct 2020 17:08:26

US3142137

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	19 Oct 2020 17:08:26

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:41:39
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:41:39
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:42:28
DataPoint Un-verified.		05 Jan 2021 21:42:07
DataPoint Verified.		16 Oct 2020 15:41:39
User entered '14:33'	Meghan York (b) (4)	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '6 Aug 2020 14:33'	System	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:41:39
User entered '72' in	Meghan York (b) (4)	07 Aug 2020 14:51:39
DataPoint set to visible.	(b) (4) System	06 Aug 2020 20:49:42

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:41:39
User entered '200' lb	Meghan York (b) (4)	07 Aug 2020 14:51:39
DataPoint set to visible.	(b) (4) System	06 Aug 2020 20:49:42

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
Amendment Manager: User entered '27.18159'	System	16 Sep 2020 23:46:11
User entered '27.2'	System	07 Aug 2020 14:51:39
DataPoint set to visible.	System	06 Aug 2020 20:49:42

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'kg/m2'	System	07 Aug 2020 14:51:39
DataPoint set to visible.	System	06 Aug 2020 20:49:42

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:41:39
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).		30 Sep 2020 16:54:36
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:47:43
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Sep 2020 19:13:27
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	21 Sep 2020 19:13:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:13:27
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:46:11

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM). User entered '96.7' F	(b) (4), (b) (6) Meghan York (b) (4) (b) (4)	28 Aug 2020 14:52:12 07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:41:39
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:13:27
User entered 'Other (Other)'	Meghan York (b) (4)	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:41:39
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:13:27
User entered 'temporal'	Meghan York (b) (4)	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:41:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:13:27
User entered '72'	Meghan York (b) (4)	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'bpm'	System	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:41:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:13:27
User entered '16'	Meghan York (b) (4)	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'breaths/min'	System	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:41:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:13:27
User entered '148'	Meghan York (b) (4)	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'mmHg'	System	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:41:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:13:27
User entered '76'	Meghan York (b) (4)	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'mmHg'	System	07 Aug 2020 14:51:39

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41

US3142137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41

US3142137

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:42:31
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:51:50

US3142137

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:42:31
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).		08 Sep 2020 04:50:35
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		04 Sep 2020 22:14:22
User entered '6 Aug 2020'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:51:50

US3142137

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:30:06
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:52:14

US3142137

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:25:34

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:30:06
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:14

US3142137

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:25:34

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:30:06
User entered 'Surgically sterile (SURGICALLY STERILE)'	Meghan York (b) (4)	07 Aug 2020 14:52:14

US3142137

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:25:34

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:30:06
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:52:14

US3142137

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:25:34

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:30:06
User entered 'UN UNK 2009'	Meghan York (b) (4)	07 Aug 2020 14:52:14

US3142137

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:25:34

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:30:06
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:52:14

US3142137

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:30:06
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:52:14

US3142137

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:25:34

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:30:06
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:52:14

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:33

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:52:33

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User entered '0'	(b) (4) Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:52:33

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered 'I'	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User entered '0'	(b) (4) Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:25:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:43:23
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:52:33

US3142137

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User closed query 'Please verify if following Safety Calls have been performed as there are no entries in EDC and no source documentation. Days 8,15,22, 36, 43 and 50' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 22:35:01
Query 'Please verify if following Safety Calls have been performed as there are no entries in EDC and no source documentation. Days 8,15,22, 36, 43 and 50' answered with 'done ' (Site from CRA).	Jill York (b) (4)	16 Feb 2021 18:43:51
User opened query 'Please verify if following Safety Calls have been performed as there are no entries in EDC and no source documentation. Days 8,15,22, 36, 43 and 50' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:38:58
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:44:25
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:52:46

US3142137

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:44:25
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:52:46

US3142137

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:44:25
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	07 Aug 2020 14:52:46

US3142137

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'VISIT1'	System	07 Aug 2020 14:52:46

US3142137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:47:13
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:09:18

US3142137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:25:34

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:47:13
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:39:21
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:39:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 20:09:18
User entered '101737' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:09:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:25:34

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:47:13
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:09:18

US3142137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:25:34

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)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:47:13
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Randomization

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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)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:47:13
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:57

US3142137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:25:34

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:47:13
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:47:13
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:25:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:47:13
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:52:57

US3142137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:25:34

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:26:48
User entered 'No (N)'	Jill York (b) (4)	11 Feb 2021 17:42:34
DataPoint set to visible.	System	09 Dec 2020 23:18:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:09:34

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:48:30
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 16:54:45
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:47:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:14:23
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:31:15
User entered '72' in	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:48:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:14:23
User entered '200' lb	Meghan York (b) (4)	07 Aug 2020 14:55:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:48:30
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 16:54:45
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:47:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:14:23
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:31:15
User entered '72' in	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:48:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:14:23
User entered '200' lb	Meghan York (b) (4)	07 Aug 2020 14:55:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:55:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	19 Oct 2020 17:13:39
User entered '14:00' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	19 Oct 2020 17:13:39
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	07 Aug 2020 14:55:25
User entered '14:33'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered '6 Aug 2020 14:00'	System	19 Oct 2020 17:13:39
User entered '6 Aug 2020 14:33'	System	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Oct 2020 16:37:29
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'temporal scanner was used.	Meghan York (b) (4) (b) (4)	19 Oct 2020 17:13:59
Temperature is not out of range ' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:46:11
User entered '96.7' F	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered 'Other (Other)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered 'temporal'	Meghan York (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered '72'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'bpm'	System	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered '16'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'breaths/min'	System	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered '148'	Meghan York (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'mmHg'	System	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered '76'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'mmHg'	System	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:48:30
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 16:54:45
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:47:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:14:23
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:31:15
User entered '72' in	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:48:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:14:23
User entered '200' lb	Meghan York (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered '6 Aug 2020'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).		18 Aug 2020 17:26:03
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 14:55:25
User entered '14:54'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered '6 Aug 2020 14:54'	System	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Oct 2020 16:37:35
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'temporal scanner was used.	Meghan York (b) (4) (b) (4)	19 Oct 2020 17:14:29
Temperature is not out of range ' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:46:11
User entered '96.5' F	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered 'Other (Other)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered 'temporal'	Meghan York (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered '74'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'bpm'	System	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered '12'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'breaths/min'	System	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered '128'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'mmHg'	System	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:28:05
User entered '92'	Meghan York (b) (4)	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'mmHg'	System	07 Aug 2020 14:55:25

US3142137

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:48:58
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4)	25 Sep 2020 18:48:06
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:58:08

US3142137

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:48:58
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	25 Sep 2020 18:48:06
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:58:08

US3142137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:49:41
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 20:50:17

US3142137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:49:41
User entered empty.	Meghan York (b) (4)	06 Aug 2020 20:50:17

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

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)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:49:41
User entered empty.	Meghan York (b) (4)	06 Aug 2020 20:50:17

US3142137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 20:50:17

US3142137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:49:41
User entered '6 Aug 2020'	Meghan York (b) (4)	06 Aug 2020 20:50:17

US3142137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:49:41
User entered '14:24'	Meghan York (b) (4)	06 Aug 2020 20:50:17

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered '6 Aug 2020 14:24'	System	06 Aug 2020 20:50:17

US3142137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:49:41
User entered 'Left Arm (LEFT ARM)'	Meghan York (b) (4)	06 Aug 2020 20:50:17

US3142137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
DataPoint Verified.		16 Oct 2020 15:49:41
User entered 'ONCE'	System	06 Aug 2020 20:50:17

US3142137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 20:50:17

US3142137

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:50:17
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:58:27

US3142137

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:50:17
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:58:27

US3142137

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User closed query 'Per source, blood draw was at 1420.' (Site from CRA).	(b) (4)	14 Apr 2021 17:02:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:42
Query 'Per source, blood draw was at 1420.' answered with 'time corrected' (Site from CRA).	Jill York (b) (4)	09 Apr 2021 18:38:58
User entered '14:20' reason for change: Data Entry Error	Jill York (b) (4)	09 Apr 2021 18:38:45
User opened query 'Per source, blood draw was at 1420.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:29:05
DataPoint Un-verified.	Meghan York (b) (4)	19 Oct 2020 17:14:47
User entered '14:10' reason for change: Data Entry Error	(b) (4)	19 Oct 2020 17:14:47
DataPoint Verified.	Meghan York (b) (4)	16 Oct 2020 15:50:17
User entered '14:20'	(b) (4), (b) (6)	16 Oct 2020 15:50:17
	Meghan York (b) (4)	07 Aug 2020 14:58:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered '6 Aug 2020 14:20'	System	09 Apr 2021 18:38:45
User entered '6 Aug 2020 14:10'	System	19 Oct 2020 17:14:47
User entered '6 Aug 2020 14:20'	System	07 Aug 2020 14:58:27

US3142137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:25:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User closed query 'Per source, swab collected at 1422.' (Site from CRA).	(b) (4)	
Query 'Per source, swab collected at 1422.' answered with 'corrected ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:48:40
User opened query 'Per source, swab collected at 1422.' (Site from CRA).	Jill York (b) (4)	13 Apr 2021 17:48:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:30:01
		22 Oct 2020 03:10:42
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:58:45
	(b) (4)	

US3142137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:25:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:58:45

US3142137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 03:10:45
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:58:45

US3142137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:25:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:48:44
DataPoint Un-verified.	Jill York (b) (4)	13 Apr 2021 17:47:59
User entered '14:22' reason for change: Data Entry Error	Jill York (b) (4)	13 Apr 2021 17:47:59
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 03:10:47
User closed query 'Please reconcile time with SD. ' (Site from CRA).		22 Oct 2020 03:10:39
User entered '14:10' reason for change: Data Entry Error	Meghan York (b) (4)	19 Oct 2020 17:14:59
Query 'Please reconcile time with SD. ' answered with 'done' (Site from CRA).	Meghan York (b) (4)	19 Oct 2020 17:08:52
User opened query 'Please reconcile time with SD. ' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 15:53:30
User entered '14:20'	Meghan York (b) (4)	07 Aug 2020 14:58:45

US3142137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:25:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered '6 Aug 2020 14:22'	System	13 Apr 2021 17:47:59
User entered '6 Aug 2020 14:10'	System	19 Oct 2020 17:14:59
User entered '6 Aug 2020 14:20'	System	07 Aug 2020 14:58:45

US3142137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:25:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:58:45

US3142137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:48:44
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:58:45

US3142137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:25:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:48:44
User entered '14:22' reason for change: Data Entry Error	Jill York (b) (4)	13 Apr 2021 17:47:59
User entered '14:10' reason for change: Data Entry Error	Meghan York (b) (4)	19 Oct 2020 17:14:59
User entered '14:20'	Meghan York (b) (4)	07 Aug 2020 14:58:45

US3142137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:25:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered '6 Aug 2020 14:22'	System	13 Apr 2021 17:47:59
User entered '6 Aug 2020 14:10'	System	19 Oct 2020 17:14:59
User entered '6 Aug 2020 14:20'	System	07 Aug 2020 14:58:45

US3142137

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:29
Data hard locked.	(b) (4) (b) (4), (b) (6)	24 Apr 2021 06:28:06
User closed query 'Thank you for your response, but safety calls have still not been entered and no source documentation is present in subject chart. Please address.' (Site from CRA).		21 Apr 2021 01:14:38
Query 'Thank you for your response, but safety calls have still not been entered and no source documentation is present in subject chart. Please address.' answered with 'done ' (Site from CRA).	Jill York (b) (4)	24 Mar 2021 15:36:46
User opened query 'Thank you for your response, but safety calls have still not been entered and no source documentation is present in subject chart. Please address.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 16:58:03
User closed query 'Please enter the Safety Call Day 8 15 and 22 SD and EDC info.' (Site from CRA).		17 Dec 2020 16:58:03
Query 'Please enter the Safety Call Day 8 15 and 22 SD and EDC info.' answered with 'Ok.' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 21:33:54
User opened query 'Please enter the Safety Call Day 8 15 and 22 SD and EDC info.' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 16:06:36
Query 'Please enter the Safety Call Day 8 and 15 SD and EDC info.' canceled (Site from CRA).		16 Oct 2020 16:05:41
User opened query 'Please enter the Safety Call Day 8 and 15 SD and EDC info.' (Site from CRA).		16 Oct 2020 16:03:02
DataPoint Verified.		16 Oct 2020 16:00:40
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:58:48

US3142137

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered 'I'	System	07 Aug 2020 14:58:48

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:07:46', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'f6890435-84a9-4533-897d-e15226e88cac'	System	06 Aug 2020 21:08:08
User entered 'Yes (Y)'	System	06 Aug 2020 21:08:08

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:07:53', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'f6890435-84a9-4533-897d-e15226e88cac'	System	06 Aug 2020 21:08:08
User entered '96.5'	System	06 Aug 2020 21:08:08

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:07:58', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'f6890435-84a9-4533-897d-e15226e88cac'	System	06 Aug 2020 21:08:08
User entered 'No (N)'	System	06 Aug 2020 21:08:08

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:08:06', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'f6890435-84a9-4533-897d-e15226e88cac'	System	06 Aug 2020 21:08:08
User entered '06 Aug 2020 15:08'	System	06 Aug 2020 21:08:08

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Aug 2020 14:44'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Aug 2020 17:14'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:38:29', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '362bb376-415b-4e37-a53c-614ff8a8d18f'	System	07 Aug 2020 13:39:38
User entered 'Yes (Y)'	System	07 Aug 2020 13:39:38

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:39:24', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '362bb376-415b-4e37-a53c-614ff8a8d18f' User entered '97.5'	System	07 Aug 2020 13:39:38
	System	07 Aug 2020 13:39:38

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:39:29', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '362bb376-415b-4e37-a53c-614ff8a8d18f'	System	07 Aug 2020 13:39:38
User entered 'No (N)'	System	07 Aug 2020 13:39:38

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:39:35', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '362bb376-415b-4e37-a53c-614ff8a8d18f'	System	07 Aug 2020 13:39:38
User entered '07 Aug 2020 07:39'	System	07 Aug 2020 13:39:38

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Aug 2020 18:09'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 2'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:16:53', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '41e6bdac-abef-47f7-85c1-9f6c7e256d38'	System	08 Aug 2020 13:17:11
User entered 'Yes (Y)'	System	08 Aug 2020 13:17:11

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '41e6bdac-abef-47f7-85c1-9f6c7e256d38'	System	08 Aug 2020 13:17:11
User entered '95.9'	System	08 Aug 2020 13:17:11

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:04', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '41e6bdac-abef-47f7-85c1-9f6c7e256d38'	System	08 Aug 2020 13:17:11
User entered 'No (N)'	System	08 Aug 2020 13:17:11

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:09', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '41e6bdac-abef-47f7-85c1-9f6c7e256d38'	System	08 Aug 2020 13:17:11
User entered '08 Aug 2020 07:17'	System	08 Aug 2020 13:17:11

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 3'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:09', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '9374ff37-c76f-48f3-a6b9-dfb3d02ca468'	System	09 Aug 2020 16:17:27
User entered 'Yes (Y)'	System	09 Aug 2020 16:17:27

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:14', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '9374ff37-c76f-48f3-a6b9-dfb3d02ca468'	System	09 Aug 2020 16:17:27
User entered '96.8'	System	09 Aug 2020 16:17:27

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:18', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '9374ff37-c76f-48f3-a6b9-dfb3d02ca468'	System	09 Aug 2020 16:17:27
User entered 'No (N)'	System	09 Aug 2020 16:17:27

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:24', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '9374ff37-c76f-48f3-a6b9-dfb3d02ca468'	System	09 Aug 2020 16:17:27
User entered '09 Aug 2020 10:17'	System	09 Aug 2020 16:17:27

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 4'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:07:22', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '6f3bead0-e69f-4fc7-9d9f-906cd6babad2'	System	10 Aug 2020 02:07:43
User entered 'Yes (Y)'	System	10 Aug 2020 02:07:43

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:07:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '6f3bead0-e69f-4fc7-9d9f-906cd6babad2'	System	10 Aug 2020 02:07:43
User entered '96.6'	System	10 Aug 2020 02:07:43

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:07:35', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '6f3bead0-e69f-4fc7-9d9f-906cd6babad2'	System	10 Aug 2020 02:07:43
User entered 'No (N)'	System	10 Aug 2020 02:07:43

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:07:39', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '6f3bead0-e69f-4fc7-9d9f-906cd6babad2'	System	10 Aug 2020 02:07:43
User entered '09 Aug 2020 20:07'	System	10 Aug 2020 02:07:43

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 5'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T22:37:24', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'fe2c7e8d-7112-43b5-98b8-185540700219'	System	11 Aug 2020 04:37:43
User entered 'Yes (Y)'	System	11 Aug 2020 04:37:43

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T22:37:29', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'fe2c7e8d-7112-43b5-98b8-185540700219' User entered '97.3'	System	11 Aug 2020 04:37:43

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T22:37:32', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'fe2c7e8d-7112-43b5-98b8-185540700219'	System	11 Aug 2020 04:37:43
User entered 'No (N)'	System	11 Aug 2020 04:37:43

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T22:37:37', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'fe2c7e8d-7112-43b5-98b8-185540700219'	System	11 Aug 2020 04:37:43
User entered '10 Aug 2020 22:37'	System	11 Aug 2020 04:37:43

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 6'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:14:50', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'bae3c9f5-2436-48e5-b90d-8540543f43c5'	System	12 Aug 2020 01:15:06
User entered 'Yes (Y)'	System	12 Aug 2020 01:15:06

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:14:57', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'bae3c9f5-2436-48e5-b90d-8540543f43c5'	System	12 Aug 2020 01:15:06
User entered '98.2'	System	12 Aug 2020 01:15:06

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:15:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'bae3c9f5-2436-48e5-b90d-8540543f43c5'	System	12 Aug 2020 01:15:06
User entered 'No (N)'	System	12 Aug 2020 01:15:06

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:15:04', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'bae3c9f5-2436-48e5-b90d-8540543f43c5'	System	12 Aug 2020 01:15:06
User entered '11 Aug 2020 19:15'	System	12 Aug 2020 01:15:06

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 7'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:12:38', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '6a2163d4-e6cf-4629-b3d2-5ce0f1cae1a5'	System	13 Aug 2020 00:12:54
User entered 'Yes (Y)'	System	13 Aug 2020 00:12:54

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:12:43', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '6a2163d4-e6cf-4629-b3d2-5ce0f1cae1a5' User entered '97.7'	System	13 Aug 2020 00:12:54
	System	13 Aug 2020 00:12:54

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:12:46', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '6a2163d4-e6cf-4629-b3d2-5ce0f1cae1a5'	System	13 Aug 2020 00:12:54
User entered 'No (N)'	System	13 Aug 2020 00:12:54

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:12:51', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '6a2163d4-e6cf-4629-b3d2-5ce0f1cae1a5'	System	13 Aug 2020 00:12:54
User entered '12 Aug 2020 18:12'	System	13 Aug 2020 00:12:54

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:08:22', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5e41acb7-e2be-4a8f-96c1-ed091e65fde4'	System	06 Aug 2020 21:10:06
User entered 'None (1)'	System	06 Aug 2020 21:10:06

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:08:39', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5e41acb7-e2be-4a8f-96c1-ed091e65fde4'	System	06 Aug 2020 21:10:06
User entered 'No (N)'	System	06 Aug 2020 21:10:06

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:08:50', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5e41acb7-e2be-4a8f-96c1-ed091e65fde4'	System	06 Aug 2020 21:10:06
User entered 'No (N)'	System	06 Aug 2020 21:10:06

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:09:05', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5e41acb7-e2be-4a8f-96c1-ed091e65fde4'	System	06 Aug 2020 21:10:06
User entered 'None (1)'	System	06 Aug 2020 21:10:06

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:10:01', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5e41acb7-e2be-4a8f-96c1-ed091e65fde4'	System	06 Aug 2020 21:10:06
User entered '06 Aug 2020 15:10'	System	06 Aug 2020 21:10:06

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Aug 2020 14:44'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Aug 2020 17:14'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:40:30', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'cea8e7ce-4dc0-4274-86fe-cba81e70eee3'	System	07 Aug 2020 13:41:02
User entered 'None (1)'	System	07 Aug 2020 13:41:02

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:40:35', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'cea8e7ce-4dc0-4274-86fe-cba81e70eee3'	System	07 Aug 2020 13:41:02
User entered 'No (N)'	System	07 Aug 2020 13:41:02

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:40:38', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'cea8e7ce-4dc0-4274-86fe-cba81e70eee3'	System	07 Aug 2020 13:41:02
User entered 'No (N)'	System	07 Aug 2020 13:41:02

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:40:47', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'cea8e7ce-4dc0-4274-86fe-cba81e70eee3'	System	07 Aug 2020 13:41:02
User entered 'None (1)'	System	07 Aug 2020 13:41:02

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:40:58', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'cea8e7ce-4dc0-4274-86fe-cba81e70eee3'	System	07 Aug 2020 13:41:02
User entered '07 Aug 2020 07:40'	System	07 Aug 2020 13:41:02

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Aug 2020 18:09'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 2'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:16', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c1716b14-1ce1-41b4-9f5a-071a09a83350'	System	08 Aug 2020 13:17:42
User entered 'None (1)'	System	08 Aug 2020 13:17:42

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:20', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c1716b14-1ce1-41b4-9f5a-071a09a83350'	System	08 Aug 2020 13:17:42
User entered 'No (N)'	System	08 Aug 2020 13:17:42

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:23', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c1716b14-1ce1-41b4-9f5a-071a09a83350'	System	08 Aug 2020 13:17:42
User entered 'No (N)'	System	08 Aug 2020 13:17:42

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:33', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c1716b14-1ce1-41b4-9f5a-071a09a83350'	System	08 Aug 2020 13:17:42
User entered 'None (1)'	System	08 Aug 2020 13:17:42

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:40', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c1716b14-1ce1-41b4-9f5a-071a09a83350'	System	08 Aug 2020 13:17:42
User entered '08 Aug 2020 07:17'	System	08 Aug 2020 13:17:42

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 3'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3c3590bf-9291-44be-9a51-d1e12fda2a11'	System	09 Aug 2020 16:17:44
User entered 'None (1)'	System	09 Aug 2020 16:17:44

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:34', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3c3590bf-9291-44be-9a51-d1e12fda2a11'	System	09 Aug 2020 16:17:44
User entered 'No (N)'	System	09 Aug 2020 16:17:44

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:36', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3c3590bf-9291-44be-9a51-d1e12fda2a11'	System	09 Aug 2020 16:17:44
User entered 'No (N)'	System	09 Aug 2020 16:17:44

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:39', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3c3590bf-9291-44be-9a51-d1e12fda2a11'	System	09 Aug 2020 16:17:44
User entered 'None (1)'	System	09 Aug 2020 16:17:44

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:44', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3c3590bf-9291-44be-9a51-d1e12fda2a11'	System	09 Aug 2020 16:17:44
User entered '09 Aug 2020 10:17'	System	09 Aug 2020 16:17:44

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 4'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:07:46', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '001daa57-b769-412a-994b-1e1022ceeb23'	System	10 Aug 2020 02:08:04
User entered 'None (1)'	System	10 Aug 2020 02:08:04

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:07:50', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '001daa57-b769-412a-994b-1e1022ceeb23'	System	10 Aug 2020 02:08:04
User entered 'No (N)'	System	10 Aug 2020 02:08:04

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:07:52', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '001daa57-b769-412a-994b-1e1022ceeb23'	System	10 Aug 2020 02:08:04
User entered 'No (N)'	System	10 Aug 2020 02:08:04

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:07:55', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '001daa57-b769-412a-994b-1e1022ceeb23'	System	10 Aug 2020 02:08:04
User entered 'None (1)'	System	10 Aug 2020 02:08:04

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:08:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '001daa57-b769-412a-994b-1e1022ceeb23'	System	10 Aug 2020 02:08:04
User entered '09 Aug 2020 20:08'	System	10 Aug 2020 02:08:04

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 5'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:03', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'a073c754-1cbc-4c92-a080-11be5d5b307f'	System	11 Aug 2020 03:44:20
User entered 'None (1)'	System	11 Aug 2020 03:44:20

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:05', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'a073c754-1cbc-4c92-a080-11be5d5b307f'	System	11 Aug 2020 03:44:20
User entered 'No (N)'	System	11 Aug 2020 03:44:20

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:08', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'a073c754-1cbc-4c92-a080-11be5d5b307f'	System	11 Aug 2020 03:44:20
User entered 'No (N)'	System	11 Aug 2020 03:44:20

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:11', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'a073c754-1cbc-4c92-a080-11be5d5b307f'	System	11 Aug 2020 03:44:20
User entered 'None (1)'	System	11 Aug 2020 03:44:20

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:16', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'a073c754-1cbc-4c92-a080-11be5d5b307f'	System	11 Aug 2020 03:44:20
User entered '10 Aug 2020 21:44'	System	11 Aug 2020 03:44:20

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 6'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:15:07', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e9356590-8705-4b7c-ba43-81ef25ad9df2'	System	12 Aug 2020 01:15:28
User entered 'None (1)'	System	12 Aug 2020 01:15:28

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:15:10', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e9356590-8705-4b7c-ba43-81ef25ad9df2'	System	12 Aug 2020 01:15:28
User entered 'No (N)'	System	12 Aug 2020 01:15:28

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:15:13', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e9356590-8705-4b7c-ba43-81ef25ad9df2'	System	12 Aug 2020 01:15:28
User entered 'No (N)'	System	12 Aug 2020 01:15:28

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:15:15', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e9356590-8705-4b7c-ba43-81ef25ad9df2'	System	12 Aug 2020 01:15:28
User entered 'None (1)'	System	12 Aug 2020 01:15:28

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:15:25', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e9356590-8705-4b7c-ba43-81ef25ad9df2'	System	12 Aug 2020 01:15:28
User entered '11 Aug 2020 19:15'	System	12 Aug 2020 01:15:28

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 7'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:12:56', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'affbf2f8-2acd-47a4-9180-a22406b2a238'	System	13 Aug 2020 00:13:10
User entered 'None (1)'	System	13 Aug 2020 00:13:10

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:12:59', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'affbf2f8-2acd-47a4-9180-a22406b2a238'	System	13 Aug 2020 00:13:10
User entered 'No (N)'	System	13 Aug 2020 00:13:10

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:01', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'affbf2f8-2acd-47a4-9180-a22406b2a238'	System	13 Aug 2020 00:13:10
User entered 'No (N)'	System	13 Aug 2020 00:13:10

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:03', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'affbf2f8-2acd-47a4-9180-a22406b2a238'	System	13 Aug 2020 00:13:10
User entered 'None (1)'	System	13 Aug 2020 00:13:10

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:07', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'affbf2f8-2acd-47a4-9180-a22406b2a238'	System	13 Aug 2020 00:13:10
User entered '12 Aug 2020 18:13'	System	13 Aug 2020 00:13:10

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:10:19', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c87c4a61-e0d3-4295-9ff0-d9591fc4f3c2'	System	06 Aug 2020 21:10:56
User entered 'None (0)'	System	06 Aug 2020 21:10:56

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:10:22', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c87c4a61-e0d3-4295-9ff0-d9591fc4f3c2'	System	06 Aug 2020 21:10:56
User entered 'None (0)'	System	06 Aug 2020 21:10:56

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:10:24', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c87c4a61-e0d3-4295-9ff0-d9591fc4f3c2'	System	06 Aug 2020 21:10:56
User entered 'None (0)'	System	06 Aug 2020 21:10:56

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:10:27', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c87c4a61-e0d3-4295-9ff0-d9591fc4f3c2'	System	06 Aug 2020 21:10:56
User entered 'None (0)'	System	06 Aug 2020 21:10:56

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:10:29', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c87c4a61-e0d3-4295-9ff0-d9591fc4f3c2'	System	06 Aug 2020 21:10:56
User entered 'None (0)'	System	06 Aug 2020 21:10:56

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:10:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c87c4a61-e0d3-4295-9ff0-d9591fc4f3c2'	System	06 Aug 2020 21:10:56
User entered 'None (0)'	System	06 Aug 2020 21:10:56

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:10:44', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c87c4a61-e0d3-4295-9ff0-d9591fc4f3c2'	System	06 Aug 2020 21:10:56
User entered 'No (N)'	System	06 Aug 2020 21:10:56

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-06T15:10:52', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c87c4a61-e0d3-4295-9ff0-d9591fc4f3c2'	System	06 Aug 2020 21:10:56
User entered '06 Aug 2020 15:10'	System	06 Aug 2020 21:10:56

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Aug 2020 14:44'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Aug 2020 17:14'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:41:08', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '76b8ce88-1e17-4a8f-99fe-a5e88496bd41'	System	07 Aug 2020 13:41:39
User entered 'None (0)'	System	07 Aug 2020 13:41:39

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:41:11', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '76b8ce88-1e17-4a8f-99fe-a5e88496bd41'	System	07 Aug 2020 13:41:39
User entered 'None (0)'	System	07 Aug 2020 13:41:39

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:41:15', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '76b8ce88-1e17-4a8f-99fe-a5e88496bd41'	System	07 Aug 2020 13:41:39
User entered 'None (0)'	System	07 Aug 2020 13:41:39

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:41:19', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '76b8ce88-1e17-4a8f-99fe-a5e88496bd41'	System	07 Aug 2020 13:41:39
User entered 'None (0)'	System	07 Aug 2020 13:41:39

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:41:22', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '76b8ce88-1e17-4a8f-99fe-a5e88496bd41'	System	07 Aug 2020 13:41:39
User entered 'None (0)'	System	07 Aug 2020 13:41:39

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:41:24', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '76b8ce88-1e17-4a8f-99fe-a5e88496bd41'	System	07 Aug 2020 13:41:39
User entered 'None (0)'	System	07 Aug 2020 13:41:39

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:41:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '76b8ce88-1e17-4a8f-99fe-a5e88496bd41'	System	07 Aug 2020 13:41:39
User entered 'No (N)'	System	07 Aug 2020 13:41:39

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-07T07:41:36', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '76b8ce88-1e17-4a8f-99fe-a5e88496bd41'	System	07 Aug 2020 13:41:39
User entered '07 Aug 2020 07:41'	System	07 Aug 2020 13:41:39

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Aug 2020 18:09'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 2'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:46', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6de1588-c8b4-4152-a1a2-983dc3c3080a'	System	08 Aug 2020 13:18:16
User entered 'None (0)'	System	08 Aug 2020 13:18:16

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:50', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6de1588-c8b4-4152-a1a2-983dc3c3080a'	System	08 Aug 2020 13:18:16
User entered 'None (0)'	System	08 Aug 2020 13:18:16

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:53', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6de1588-c8b4-4152-a1a2-983dc3c3080a'	System	08 Aug 2020 13:18:16
User entered 'None (0)'	System	08 Aug 2020 13:18:16

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:56', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6de1588-c8b4-4152-a1a2-983dc3c3080a'	System	08 Aug 2020 13:18:16
User entered 'None (0)'	System	08 Aug 2020 13:18:16

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:17:59', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6de1588-c8b4-4152-a1a2-983dc3c3080a'	System	08 Aug 2020 13:18:16
User entered 'None (0)'	System	08 Aug 2020 13:18:16

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:18:02', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6de1588-c8b4-4152-a1a2-983dc3c3080a'	System	08 Aug 2020 13:18:16
User entered 'None (0)'	System	08 Aug 2020 13:18:16

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:18:07', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6de1588-c8b4-4152-a1a2-983dc3c3080a'	System	08 Aug 2020 13:18:16
User entered 'No (N)'	System	08 Aug 2020 13:18:16

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-08T07:18:13', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6de1588-c8b4-4152-a1a2-983dc3c3080a'	System	08 Aug 2020 13:18:16
User entered '08 Aug 2020 07:18'	System	08 Aug 2020 13:18:16

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 3'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:49', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '870f8261-16ed-4c20-a98a-e1272054bf23'	System	09 Aug 2020 16:18:10
User entered 'None (0)'	System	09 Aug 2020 16:18:10

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:52', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '870f8261-16ed-4c20-a98a-e1272054bf23'	System	09 Aug 2020 16:18:10
User entered 'None (0)'	System	09 Aug 2020 16:18:10

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:54', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '870f8261-16ed-4c20-a98a-e1272054bf23'	System	09 Aug 2020 16:18:10
User entered 'None (0)'	System	09 Aug 2020 16:18:10

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:56', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '870f8261-16ed-4c20-a98a-e1272054bf23'	System	09 Aug 2020 16:18:10
User entered 'None (0)'	System	09 Aug 2020 16:18:10

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:17:58', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '870f8261-16ed-4c20-a98a-e1272054bf23'	System	09 Aug 2020 16:18:10
User entered 'None (0)'	System	09 Aug 2020 16:18:10

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:18:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '870f8261-16ed-4c20-a98a-e1272054bf23'	System	09 Aug 2020 16:18:10
User entered 'None (0)'	System	09 Aug 2020 16:18:10

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:18:05', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '870f8261-16ed-4c20-a98a-e1272054bf23'	System	09 Aug 2020 16:18:10
User entered 'No (N)'	System	09 Aug 2020 16:18:10

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T10:18:10', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '870f8261-16ed-4c20-a98a-e1272054bf23'	System	09 Aug 2020 16:18:10
User entered '09 Aug 2020 10:18'	System	09 Aug 2020 16:18:10

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 4'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:08:05', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7902149-7b0b-4e2d-8e90-40e90624d772'	System	10 Aug 2020 02:08:26
User entered 'None (0)'	System	10 Aug 2020 02:08:26

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:08:07', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7902149-7b0b-4e2d-8e90-40e90624d772'	System	10 Aug 2020 02:08:26
User entered 'None (0)'	System	10 Aug 2020 02:08:26

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:08:09', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7902149-7b0b-4e2d-8e90-40e90624d772'	System	10 Aug 2020 02:08:26
User entered 'None (0)'	System	10 Aug 2020 02:08:26

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:08:12', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7902149-7b0b-4e2d-8e90-40e90624d772'	System	10 Aug 2020 02:08:26
User entered 'None (0)'	System	10 Aug 2020 02:08:26

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:08:14', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7902149-7b0b-4e2d-8e90-40e90624d772'	System	10 Aug 2020 02:08:26
User entered 'None (0)'	System	10 Aug 2020 02:08:26

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:08:16', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7902149-7b0b-4e2d-8e90-40e90624d772'	System	10 Aug 2020 02:08:26
User entered 'None (0)'	System	10 Aug 2020 02:08:26

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:08:19', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7902149-7b0b-4e2d-8e90-40e90624d772'	System	10 Aug 2020 02:08:26
User entered 'No (N)'	System	10 Aug 2020 02:08:26

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-09T20:08:24', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7902149-7b0b-4e2d-8e90-40e90624d772'	System	10 Aug 2020 02:08:26
User entered '09 Aug 2020 20:08'	System	10 Aug 2020 02:08:26

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 5'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:21', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a769ab7-2deb-4c8d-8262-1c394e1276dc'	System	11 Aug 2020 03:44:48
User entered 'None (0)'	System	11 Aug 2020 03:44:48

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:24', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a769ab7-2deb-4c8d-8262-1c394e1276dc'	System	11 Aug 2020 03:44:48
User entered 'None (0)'	System	11 Aug 2020 03:44:48

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:26', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a769ab7-2deb-4c8d-8262-1c394e1276dc'	System	11 Aug 2020 03:44:48
User entered 'None (0)'	System	11 Aug 2020 03:44:48

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:28', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a769ab7-2deb-4c8d-8262-1c394e1276dc'	System	11 Aug 2020 03:44:48
User entered 'None (0)'	System	11 Aug 2020 03:44:48

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a769ab7-2deb-4c8d-8262-1c394e1276dc'	System	11 Aug 2020 03:44:48
User entered 'None (0)'	System	11 Aug 2020 03:44:48

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:33', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a769ab7-2deb-4c8d-8262-1c394e1276dc'	System	11 Aug 2020 03:44:48
User entered 'None (0)'	System	11 Aug 2020 03:44:48

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:38', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a769ab7-2deb-4c8d-8262-1c394e1276dc'	System	11 Aug 2020 03:44:48
User entered 'No (N)'	System	11 Aug 2020 03:44:48

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-10T21:44:44', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a769ab7-2deb-4c8d-8262-1c394e1276dc'	System	11 Aug 2020 03:44:48
User entered '10 Aug 2020 21:44'	System	11 Aug 2020 03:44:48

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 6'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:14:04', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '7d5af72e-ecc0-4bda-9493-69a87e83ea0c'	System	12 Aug 2020 01:14:34
User entered 'None (0)'	System	12 Aug 2020 01:14:34

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:14:13', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '7d5af72e-ecc0-4bda-9493-69a87e83ea0c'	System	12 Aug 2020 01:14:34
User entered 'No interference with activity (1)'	System	12 Aug 2020 01:14:34

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:14:16', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '7d5af72e-ecc0-4bda-9493-69a87e83ea0c'	System	12 Aug 2020 01:14:34
User entered 'None (0)'	System	12 Aug 2020 01:14:34

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:14:18', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '7d5af72e-ecc0-4bda-9493-69a87e83ea0c'	System	12 Aug 2020 01:14:34
User entered 'None (0)'	System	12 Aug 2020 01:14:34

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:14:20', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '7d5af72e-ecc0-4bda-9493-69a87e83ea0c'	System	12 Aug 2020 01:14:34
User entered 'None (0)'	System	12 Aug 2020 01:14:34

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:14:23', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '7d5af72e-ecc0-4bda-9493-69a87e83ea0c'	System	12 Aug 2020 01:14:34
User entered 'None (0)'	System	12 Aug 2020 01:14:34

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:14:27', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '7d5af72e-ecc0-4bda-9493-69a87e83ea0c'	System	12 Aug 2020 01:14:34
User entered 'No (N)'	System	12 Aug 2020 01:14:34

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-11T19:14:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '7d5af72e-ecc0-4bda-9493-69a87e83ea0c'	System	12 Aug 2020 01:14:34
User entered '11 Aug 2020 19:14'	System	12 Aug 2020 01:14:34

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 7'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:11', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'aa6ec009-0334-425a-87b4-0156a980c779'	System	13 Aug 2020 00:13:33
User entered 'None (0)'	System	13 Aug 2020 00:13:33

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:13', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'aa6ec009-0334-425a-87b4-0156a980c779'	System	13 Aug 2020 00:13:33
User entered 'None (0)'	System	13 Aug 2020 00:13:33

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:15', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'aa6ec009-0334-425a-87b4-0156a980c779'	System	13 Aug 2020 00:13:33
User entered 'None (0)'	System	13 Aug 2020 00:13:33

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:17', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'aa6ec009-0334-425a-87b4-0156a980c779'	System	13 Aug 2020 00:13:33
User entered 'None (0)'	System	13 Aug 2020 00:13:33

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:19', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'aa6ec009-0334-425a-87b4-0156a980c779'	System	13 Aug 2020 00:13:33
User entered 'None (0)'	System	13 Aug 2020 00:13:33

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:21', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'aa6ec009-0334-425a-87b4-0156a980c779'	System	13 Aug 2020 00:13:33
User entered 'None (0)'	System	13 Aug 2020 00:13:33

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:24', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'aa6ec009-0334-425a-87b4-0156a980c779'	System	13 Aug 2020 00:13:33
User entered 'No (N)'	System	13 Aug 2020 00:13:33

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-12T18:13:29', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'aa6ec009-0334-425a-87b4-0156a980c779'	System	13 Aug 2020 00:13:33
User entered '12 Aug 2020 18:13'	System	13 Aug 2020 00:13:33

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	12 Aug 2020 01:14:34
User entered 'Day 8'	System	12 Aug 2020 01:14:34

US3142137

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-13T21:52:17', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8ae0c076-8c22-4a4e-976c-fdea7cd2fe16'	System	14 Aug 2020 03:52:25
User entered 'No (N)'	System	14 Aug 2020 03:52:25

US3142137

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-08-13T21:52:21', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8ae0c076-8c22-4a4e-976c-fdea7cd2fe16'	System	14 Aug 2020 03:52:25
User entered '13 Aug 2020 21:52'	System	14 Aug 2020 03:52:25

US3142137

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 01:14:34

US3142137

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 01:14:34

US3142137

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:21:16
User entered 'Yes (Y)'	Jill York (b) (4)	08 Feb 2021 20:48:23

US3142137

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:21:16
User entered '13 Aug 2020'	Jill York (b) (4)	08 Feb 2021 20:48:23

US3142137

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:21:16
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	08 Feb 2021 20:48:23

US3142137

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:21:16
User entered empty.	Jill York (b) (4)	08 Feb 2021 20:48:23

US3142137

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:21:27
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:13:50

US3142137

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered 'I'	System	04 Sep 2020 22:13:50

US3142137

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:21:50
User entered 'Yes (Y)'	Jill York (b) (4)	08 Feb 2021 20:48:48

US3142137

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:21:50
User entered '21 Aug 2020'	Jill York (b) (4)	08 Feb 2021 20:48:48

US3142137

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:21:50
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	08 Feb 2021 20:48:48

US3142137

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:21:50
User entered empty.	Jill York (b) (4)	08 Feb 2021 20:48:48

US3142137

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:22:08
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:13:58

US3142137

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered 'I'	System	04 Sep 2020 22:13:58

US3142137

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:22:21
User entered 'Yes (Y)'	Jill York (b) (4)	08 Feb 2021 20:49:03

US3142137

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:22:21
User entered '28 Aug 2020'	Jill York (b) (4)	08 Feb 2021 20:49:03

US3142137

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:22:21
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	08 Feb 2021 20:49:03

US3142137

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:22:21
User entered empty.	Jill York (b) (4)	08 Feb 2021 20:49:03

US3142137

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:22:43
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:14:08

US3142137

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered 'I'	System	04 Sep 2020 22:14:08

US3142137

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:53:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Information is correct. Now complete ' (Site from DM).	Meghan York (b) (4)	21 Oct 2020 16:33:51
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 08:59:51
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:07:22
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:14:22

US3142137

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:07:22
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:14:22

US3142137

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:07:22
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	04 Sep 2020 22:14:22

US3142137

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'VISIT2'	System	04 Sep 2020 22:14:22

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '14:35'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered '4 Sep 2020 14:35'	System	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '97.5' F	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered 'Other (Other)'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered 'temporal'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '88'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'bpm'	System	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '12'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'breaths/min'	System	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '116'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'mmHg'	System	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '80'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'mmHg'	System	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '15:33'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered '4 Sep 2020 15:33'	System	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:31:43
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Oct 2020 16:41:35
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'temporal scanner was used.	Meghan York (b) (4) (b) (4)	19 Oct 2020 17:15:44
Temperature is not out of range ' (Site from System). DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:36
DataPoint Verified.		16 Oct 2020 16:08:00
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:46:11
User entered '96.4' F	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered 'Other (Other)'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered 'temporal'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '75'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'bpm'	System	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '11'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'breaths/min'	System	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '126'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'mmHg'	System	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:08:00
User entered '64'	Meghan York (b) (4)	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'mmHg'	System	04 Sep 2020 22:16:33

US3142137

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:32:34
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:17:27

US3142137

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:32:34
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:17:27

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:11:17
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:17:15

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:11:17
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:17:15

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

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)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:11:17
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:17:15

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 22:17:15

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:11:17
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:17:15

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:11:17
User entered '15:03'	Meghan York (b) (4)	04 Sep 2020 22:17:15

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered '4 Sep 2020 15:03'	System	04 Sep 2020 22:17:15

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:11:17
User entered 'Left Arm (LEFT ARM)'	Meghan York (b) (4)	04 Sep 2020 22:17:15

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
DataPoint Verified.		16 Oct 2020 16:11:17
User entered 'ONCE'	System	04 Sep 2020 22:17:15

US3142137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 22:17:15

US3142137

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:11:51
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:17:44

US3142137

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:11:56
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:17:44

US3142137

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:11:57
User entered '14:42'	Meghan York (b) (4)	04 Sep 2020 22:17:44

US3142137

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered '4 Sep 2020 14:42'	System	04 Sep 2020 22:17:44

US3142137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:25:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:13:08
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:18:05

US3142137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:25:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:18:05

US3142137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:15
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:18:05

US3142137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:25:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:15
User entered '14:38'	Meghan York (b) (4)	04 Sep 2020 22:18:05

US3142137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:25:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered '4 Sep 2020 14:38'	System	04 Sep 2020 22:18:05

US3142137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:25:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:18:05

US3142137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:15
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:18:05

US3142137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:25:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:15
User entered '14:38'	Meghan York (b) (4)	04 Sep 2020 22:18:05

US3142137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:25:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered '4 Sep 2020 14:38'	System	04 Sep 2020 22:18:05

US3142137

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:12:11
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:18:09

US3142137

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'I'	System	04 Sep 2020 22:18:09

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '04 Sep 2020 15:23'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '04 Sep 2020 17:53'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '04 Sep 2020 18:48'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 2'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:54:19', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'd5aed889-cafc-4033-a701-928acc166a99'	System	06 Sep 2020 03:54:38
User entered 'Yes (Y)'	System	06 Sep 2020 03:54:38

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:54:28', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'd5aed889-cafc-4033-a701-928acc166a99'	System	06 Sep 2020 03:54:38
User entered '97.0'	System	06 Sep 2020 03:54:38

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:54:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'd5aed889-cafc-4033-a701-928acc166a99'	System	06 Sep 2020 03:54:38
User entered 'No (N)'	System	06 Sep 2020 03:54:38

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:54:36', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'd5aed889-cafc-4033-a701-928acc166a99'	System	06 Sep 2020 03:54:38
User entered '05 Sep 2020 21:54'	System	06 Sep 2020 03:54:38

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 3'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:06', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5fcc850d-2d72-4b75-a8af-da6395433ed9'	System	07 Sep 2020 04:24:23
User entered 'Yes (Y)'	System	07 Sep 2020 04:24:23

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:12', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5fcc850d-2d72-4b75-a8af-da6395433ed9'	System	07 Sep 2020 04:24:23
User entered '97.2'	System	07 Sep 2020 04:24:23

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:15', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5fcc850d-2d72-4b75-a8af-da6395433ed9'	System	07 Sep 2020 04:24:23
User entered 'No (N)'	System	07 Sep 2020 04:24:23

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:19', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5fcc850d-2d72-4b75-a8af-da6395433ed9'	System	07 Sep 2020 04:24:23
User entered '06 Sep 2020 22:24'	System	07 Sep 2020 04:24:23

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 4'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:13:41', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '796f100e-e314-4c26-bc3c-7c53e928b73b'	System	08 Sep 2020 02:13:58
User entered 'Yes (Y)'	System	08 Sep 2020 02:13:58

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:13:47', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '796f100e-e314-4c26-bc3c-7c53e928b73b'	System	08 Sep 2020 02:13:58
User entered '97.0'	System	08 Sep 2020 02:13:58

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:13:49', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '796f100e-e314-4c26-bc3c-7c53e928b73b'	System	08 Sep 2020 02:13:58
User entered 'No (N)'	System	08 Sep 2020 02:13:58

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:13:55', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '796f100e-e314-4c26-bc3c-7c53e928b73b'	System	08 Sep 2020 02:13:58
User entered '07 Sep 2020 20:13'	System	08 Sep 2020 02:13:58

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 5'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:32:34', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '2b3a9735-97af-4fb5-866a-1394e0114fcc'	System	09 Sep 2020 04:32:50
User entered 'Yes (Y)'	System	09 Sep 2020 04:32:50

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:32:41', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '2b3a9735-97af-4fb5-866a-1394e0114fcc'	System	09 Sep 2020 04:32:50
User entered '97.1'	System	09 Sep 2020 04:32:50

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:32:44', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '2b3a9735-97af-4fb5-866a-1394e0114fcc'	System	09 Sep 2020 04:32:50
User entered 'No (N)'	System	09 Sep 2020 04:32:50

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:32:48', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '2b3a9735-97af-4fb5-866a-1394e0114fcc'	System	09 Sep 2020 04:32:50
User entered '08 Sep 2020 22:32'	System	09 Sep 2020 04:32:50

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 6'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:51:28', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3b90b331-0128-4af7-bddb-f64423fd011e'	System	10 Sep 2020 01:51:42
User entered 'Yes (Y)'	System	10 Sep 2020 01:51:42

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:51:34', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3b90b331-0128-4af7-bddb-f64423fd011e'	System	10 Sep 2020 01:51:42
User entered '97.1'	System	10 Sep 2020 01:51:42

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:51:37', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3b90b331-0128-4af7-bddb-f64423fd011e'	System	10 Sep 2020 01:51:42
User entered 'No (N)'	System	10 Sep 2020 01:51:42

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:51:41', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3b90b331-0128-4af7-bddb-f64423fd011e'	System	10 Sep 2020 01:51:42
User entered '09 Sep 2020 19:51'	System	10 Sep 2020 01:51:42

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 7'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '04 Sep 2020 15:23'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '04 Sep 2020 17:53'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '04 Sep 2020 18:48'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 2'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:54:41', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7e6552d-8a19-4275-82bd-fb84031f93db'	System	06 Sep 2020 03:54:59
User entered 'None (1)'	System	06 Sep 2020 03:54:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:54:44', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7e6552d-8a19-4275-82bd-fb84031f93db'	System	06 Sep 2020 03:54:59
User entered 'No (N)'	System	06 Sep 2020 03:54:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:54:46', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7e6552d-8a19-4275-82bd-fb84031f93db'	System	06 Sep 2020 03:54:59
User entered 'No (N)'	System	06 Sep 2020 03:54:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:54:49', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7e6552d-8a19-4275-82bd-fb84031f93db'	System	06 Sep 2020 03:54:59
User entered 'None (1)'	System	06 Sep 2020 03:54:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:54:55', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e7e6552d-8a19-4275-82bd-fb84031f93db'	System	06 Sep 2020 03:54:59
User entered '05 Sep 2020 21:54'	System	06 Sep 2020 03:54:59

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 3'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:23', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5e39f955-d569-458f-809a-d624562023dc'	System	07 Sep 2020 04:24:40
User entered 'None (1)'	System	07 Sep 2020 04:24:40

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:26', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5e39f955-d569-458f-809a-d624562023dc'	System	07 Sep 2020 04:24:40
User entered 'No (N)'	System	07 Sep 2020 04:24:40

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:28', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5e39f955-d569-458f-809a-d624562023dc'	System	07 Sep 2020 04:24:40
User entered 'No (N)'	System	07 Sep 2020 04:24:40

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:30', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5e39f955-d569-458f-809a-d624562023dc'	System	07 Sep 2020 04:24:40
User entered 'None (1)'	System	07 Sep 2020 04:24:40

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:34', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5e39f955-d569-458f-809a-d624562023dc'	System	07 Sep 2020 04:24:40
User entered '06 Sep 2020 22:24'	System	07 Sep 2020 04:24:40

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 4'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5f9755f1-e3b6-434a-aa41-b6b9cb240176'	System	08 Sep 2020 02:14:15
User entered 'None (1)'	System	08 Sep 2020 02:14:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:02', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5f9755f1-e3b6-434a-aa41-b6b9cb240176'	System	08 Sep 2020 02:14:15
User entered 'No (N)'	System	08 Sep 2020 02:14:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:06', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5f9755f1-e3b6-434a-aa41-b6b9cb240176'	System	08 Sep 2020 02:14:15
User entered 'No (N)'	System	08 Sep 2020 02:14:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:08', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5f9755f1-e3b6-434a-aa41-b6b9cb240176'	System	08 Sep 2020 02:14:15
User entered 'None (1)'	System	08 Sep 2020 02:14:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:13', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '5f9755f1-e3b6-434a-aa41-b6b9cb240176'	System	08 Sep 2020 02:14:15
User entered '07 Sep 2020 20:14'	System	08 Sep 2020 02:14:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 5'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:32:52', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b4bd1858-5984-49d8-9b4e-fa0905780bd6'	System	09 Sep 2020 04:33:08
User entered 'None (1)'	System	09 Sep 2020 04:33:08

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:32:55', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b4bd1858-5984-49d8-9b4e-fa0905780bd6'	System	09 Sep 2020 04:33:08
User entered 'No (N)'	System	09 Sep 2020 04:33:08

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:32:57', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b4bd1858-5984-49d8-9b4e-fa0905780bd6'	System	09 Sep 2020 04:33:08
User entered 'No (N)'	System	09 Sep 2020 04:33:08

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:32:59', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b4bd1858-5984-49d8-9b4e-fa0905780bd6'	System	09 Sep 2020 04:33:08
User entered 'None (1)'	System	09 Sep 2020 04:33:08

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:33:03', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b4bd1858-5984-49d8-9b4e-fa0905780bd6'	System	09 Sep 2020 04:33:08
User entered '08 Sep 2020 22:33'	System	09 Sep 2020 04:33:08

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 6'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:51:45', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8c2f69e1-ca2d-4eb3-9efb-d5eb1f15834d'	System	10 Sep 2020 01:51:56
User entered 'None (1)'	System	10 Sep 2020 01:51:56

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:51:47', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8c2f69e1-ca2d-4eb3-9efb-d5eb1f15834d'	System	10 Sep 2020 01:51:56
User entered 'No (N)'	System	10 Sep 2020 01:51:56

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:51:49', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8c2f69e1-ca2d-4eb3-9efb-d5eb1f15834d'	System	10 Sep 2020 01:51:56
User entered 'No (N)'	System	10 Sep 2020 01:51:56

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:51:51', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8c2f69e1-ca2d-4eb3-9efb-d5eb1f15834d'	System	10 Sep 2020 01:51:56
User entered 'None (1)'	System	10 Sep 2020 01:51:56

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:51:55', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8c2f69e1-ca2d-4eb3-9efb-d5eb1f15834d'	System	10 Sep 2020 01:51:56
User entered '09 Sep 2020 19:51'	System	10 Sep 2020 01:51:56

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 7'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '04 Sep 2020 15:23'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '04 Sep 2020 17:53'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '04 Sep 2020 18:48'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 2'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:55:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '23bcd9c-bbd2-4618-b909-8a2adab7fba9'	System	06 Sep 2020 03:55:21
User entered 'None (0)'	System	06 Sep 2020 03:55:21

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:55:02', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '23bcd9c-bbd2-4618-b909-8a2adab7fba9'	System	06 Sep 2020 03:55:21
User entered 'None (0)'	System	06 Sep 2020 03:55:21

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:55:04', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '23bced9c-bbd2-4618-b909-8a2adab7fba9'	System	06 Sep 2020 03:55:21
User entered 'None (0)'	System	06 Sep 2020 03:55:21

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:55:06', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '23bcd9c-bbd2-4618-b909-8a2adab7fba9'	System	06 Sep 2020 03:55:21
User entered 'None (0)'	System	06 Sep 2020 03:55:21

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:55:08', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '23bcd9c-bbd2-4618-b909-8a2adab7fba9'	System	06 Sep 2020 03:55:21
User entered 'None (0)'	System	06 Sep 2020 03:55:21

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:55:10', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '23bcd9c-bbd2-4618-b909-8a2adab7fba9'	System	06 Sep 2020 03:55:21
User entered 'None (0)'	System	06 Sep 2020 03:55:21

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:55:13', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '23bcd9c-bbd2-4618-b909-8a2adab7fba9'	System	06 Sep 2020 03:55:21
User entered 'No (N)'	System	06 Sep 2020 03:55:21

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-05T21:55:18', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '23bcd9c-bbd2-4618-b909-8a2adab7fba9'	System	06 Sep 2020 03:55:21
User entered '05 Sep 2020 21:55'	System	06 Sep 2020 03:55:21

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 3'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:39', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '38a15aa6-e7b5-4f44-b6cf-929e88c8be65'	System	07 Sep 2020 04:25:03
User entered 'None (0)'	System	07 Sep 2020 04:25:03

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:40', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '38a15aa6-e7b5-4f44-b6cf-929e88c8be65'	System	07 Sep 2020 04:25:03
User entered 'None (0)'	System	07 Sep 2020 04:25:03

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:42', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '38a15aa6-e7b5-4f44-b6cf-929e88c8be65'	System	07 Sep 2020 04:25:03
User entered 'None (0)'	System	07 Sep 2020 04:25:03

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:44', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '38a15aa6-e7b5-4f44-b6cf-929e88c8be65'	System	07 Sep 2020 04:25:03
User entered 'None (0)'	System	07 Sep 2020 04:25:03

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:46', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '38a15aa6-e7b5-4f44-b6cf-929e88c8be65'	System	07 Sep 2020 04:25:03
User entered 'None (0)'	System	07 Sep 2020 04:25:03

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:48', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '38a15aa6-e7b5-4f44-b6cf-929e88c8be65'	System	07 Sep 2020 04:25:03
User entered 'None (0)'	System	07 Sep 2020 04:25:03

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:51', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '38a15aa6-e7b5-4f44-b6cf-929e88c8be65'	System	07 Sep 2020 04:25:03
User entered 'No (N)'	System	07 Sep 2020 04:25:03

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-06T22:24:56', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '38a15aa6-e7b5-4f44-b6cf-929e88c8be65'	System	07 Sep 2020 04:25:03
User entered '06 Sep 2020 22:24'	System	07 Sep 2020 04:25:03

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 4'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:17', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dda9c9e9-5944-4bcf-af61-80a816427cea'	System	08 Sep 2020 02:14:39
User entered 'None (0)'	System	08 Sep 2020 02:14:39

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:19', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dda9c9e9-5944-4bcf-af61-80a816427cea'	System	08 Sep 2020 02:14:39
User entered 'None (0)'	System	08 Sep 2020 02:14:39

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:22', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dda9c9e9-5944-4bcf-af61-80a816427cea'	System	08 Sep 2020 02:14:39
User entered 'None (0)'	System	08 Sep 2020 02:14:39

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:24', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dda9c9e9-5944-4bcf-af61-80a816427cea'	System	08 Sep 2020 02:14:39
User entered 'None (0)'	System	08 Sep 2020 02:14:39

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:26', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dda9c9e9-5944-4bcf-af61-80a816427cea'	System	08 Sep 2020 02:14:39
User entered 'None (0)'	System	08 Sep 2020 02:14:39

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:28', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dda9c9e9-5944-4bcf-af61-80a816427cea'	System	08 Sep 2020 02:14:39
User entered 'None (0)'	System	08 Sep 2020 02:14:39

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:32', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dda9c9e9-5944-4bcf-af61-80a816427cea'	System	08 Sep 2020 02:14:39
User entered 'No (N)'	System	08 Sep 2020 02:14:39

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-07T20:14:36', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dda9c9e9-5944-4bcf-af61-80a816427cea'	System	08 Sep 2020 02:14:39
User entered '07 Sep 2020 20:14'	System	08 Sep 2020 02:14:39

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 5'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:33:07', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e495b906-6075-4e5f-8419-0abd2465f628'	System	09 Sep 2020 04:33:24
User entered 'None (0)'	System	09 Sep 2020 04:33:24

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:33:09', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e495b906-6075-4e5f-8419-0abd2465f628'	System	09 Sep 2020 04:33:24
User entered 'None (0)'	System	09 Sep 2020 04:33:24

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:33:11', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e495b906-6075-4e5f-8419-0abd2465f628'	System	09 Sep 2020 04:33:24
User entered 'None (0)'	System	09 Sep 2020 04:33:24

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:33:13', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e495b906-6075-4e5f-8419-0abd2465f628'	System	09 Sep 2020 04:33:24
User entered 'None (0)'	System	09 Sep 2020 04:33:24

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:33:15', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e495b906-6075-4e5f-8419-0abd2465f628'	System	09 Sep 2020 04:33:24
User entered 'None (0)'	System	09 Sep 2020 04:33:24

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:33:17', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e495b906-6075-4e5f-8419-0abd2465f628'	System	09 Sep 2020 04:33:24
User entered 'None (0)'	System	09 Sep 2020 04:33:24

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:33:19', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e495b906-6075-4e5f-8419-0abd2465f628'	System	09 Sep 2020 04:33:24
User entered 'No (N)'	System	09 Sep 2020 04:33:24

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-08T22:33:22', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e495b906-6075-4e5f-8419-0abd2465f628'	System	09 Sep 2020 04:33:24
User entered '08 Sep 2020 22:33'	System	09 Sep 2020 04:33:24

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 6'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:51:59', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '779264e3-c5d8-48c3-bb7f-77261e9ba389'	System	10 Sep 2020 01:52:17
User entered 'None (0)'	System	10 Sep 2020 01:52:17

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:52:01', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '779264e3-c5d8-48c3-bb7f-77261e9ba389'	System	10 Sep 2020 01:52:17
User entered 'None (0)'	System	10 Sep 2020 01:52:17

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:52:03', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '779264e3-c5d8-48c3-bb7f-77261e9ba389'	System	10 Sep 2020 01:52:17
User entered 'None (0)'	System	10 Sep 2020 01:52:17

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:52:05', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '779264e3-c5d8-48c3-bb7f-77261e9ba389'	System	10 Sep 2020 01:52:17
User entered 'None (0)'	System	10 Sep 2020 01:52:17

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:52:07', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '779264e3-c5d8-48c3-bb7f-77261e9ba389'	System	10 Sep 2020 01:52:17
User entered 'None (0)'	System	10 Sep 2020 01:52:17

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:52:09', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '779264e3-c5d8-48c3-bb7f-77261e9ba389'	System	10 Sep 2020 01:52:17
User entered 'None (0)'	System	10 Sep 2020 01:52:17

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:52:12', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '779264e3-c5d8-48c3-bb7f-77261e9ba389'	System	10 Sep 2020 01:52:17
User entered 'No (N)'	System	10 Sep 2020 01:52:17

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-09-09T19:52:15', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '779264e3-c5d8-48c3-bb7f-77261e9ba389'	System	10 Sep 2020 01:52:17
User entered '09 Sep 2020 19:52'	System	10 Sep 2020 01:52:17

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	04 Sep 2020 22:17:15
User entered 'Day 7'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 22:17:15

US3142137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:25:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 22:17:15

US3142137

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:31:44
User entered 'Yes (Y)'	Jill York (b) (4)	08 Feb 2021 18:10:11

US3142137

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:31:44
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		24 Feb 2021 06:49:17
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date is correct' (Site from System).	Jill York (b) (4)	08 Feb 2021 18:10:21
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Feb 2021 18:10:11
User entered '10 Sep 2020'	Jill York (b) (4)	08 Feb 2021 18:10:11

US3142137

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:31:44
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	08 Feb 2021 18:10:11

US3142137

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:31:44
User entered empty.	Jill York (b) (4)	08 Feb 2021 18:10:11

US3142137

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:33:32
User entered 'Yes (Y)'	Meghan York (b) (4)	21 Oct 2020 16:30:46

US3142137

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered 'I'	System	21 Oct 2020 16:30:46

US3142137

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:34:51
User entered 'Yes (Y)'	Jill York (b) (4)	08 Feb 2021 18:13:47

US3142137

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:34:51
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		24 Feb 2021 06:48:50
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Jill York (b) (4)	08 Feb 2021 18:13:56
answered with 'date is correct' (Site from System).		
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Feb 2021 18:13:47
User entered '17 Sep 2020'	Jill York (b) (4)	08 Feb 2021 18:13:47

US3142137

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:34:51
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	08 Feb 2021 18:13:47

US3142137

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:34:51
User entered empty.	Jill York (b) (4)	08 Feb 2021 18:13:47

US3142137

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:34:58
User entered 'Yes (Y)'	Meghan York (b) (4)	21 Oct 2020 16:30:53

US3142137

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered 'I'	System	21 Oct 2020 16:30:53

US3142137

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:24:37
User entered 'Yes (Y)'	Jill York (b) (4)	08 Feb 2021 18:14:38

US3142137

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:24:37
User entered '25 Sep 2020'	Jill York (b) (4)	08 Feb 2021 18:14:38

US3142137

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:24:37
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	08 Feb 2021 18:14:38

US3142137

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:24:37
User entered empty.	Jill York (b) (4)	08 Feb 2021 18:14:38

US3142137

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:25:00
User entered 'Yes (Y)'	Meghan York (b) (4)	21 Oct 2020 16:30:59

US3142137

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered 'I'	System	21 Oct 2020 16:30:59

US3142137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User closed query 'Please enter Flu shot in con meds EDC and SD if appropriate' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 16:54:58
Query 'Please enter Flu shot in con meds EDC and SD if appropriate' answered with 'added ' (Site from CRA).	Meghan York (b) (4)	25 Jan 2021 17:19:33
User opened query 'Please enter Flu shot in con meds EDC and SD if appropriate' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:25:32
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:19:54
User entered 'Yes (Y)'	Meghan York (b) (4)	21 Oct 2020 16:32:06

US3142137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:19:54
User entered '30 Sep 2020'	Meghan York (b) (4)	21 Oct 2020 16:32:06

US3142137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:19:54
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	21 Oct 2020 16:32:06

US3142137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'VISIT3'	System	21 Oct 2020 16:32:06

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:07
User entered 'Yes (Y)'	Meghan York (b) (4)	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:07
User entered '30 Sep 2020'	Meghan York (b) (4)	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:07
User entered '09:08'	Meghan York (b) (4)	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered '30 Sep 2020 09:08'	System	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:07
User entered '97.0' F	Meghan York (b) (4)	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:07
User entered 'Other (Other)'	Meghan York (b) (4)	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:07
User entered 'temporal'	Meghan York (b) (4)	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:07
User entered '73'	Meghan York (b) (4)	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'bpm'	System	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:07
User entered '12'	Meghan York (b) (4)	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'breaths/min'	System	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:07
User entered '117'	Meghan York (b) (4)	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'mmHg'	System	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:07
User entered '73'	Meghan York (b) (4)	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'mmHg'	System	21 Oct 2020 16:32:43

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08

US3142137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08

US3142137

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:41
User entered 'Yes (Y)'	Meghan York (b) (4)	21 Oct 2020 16:32:57

US3142137

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:21:41
User entered '30 Sep 2020'	Meghan York (b) (4)	21 Oct 2020 16:32:57

US3142137

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:22:01
User entered 'Yes (Y)'	Meghan York (b) (4)	21 Oct 2020 16:33:12

US3142137

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:22:01
User entered '30 Sep 2020'	Meghan York (b) (4)	21 Oct 2020 16:33:12

US3142137

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:22:01
User entered '09:17'	Meghan York (b) (4)	21 Oct 2020 16:33:12

US3142137

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered '30 Sep 2020 09:17'	System	21 Oct 2020 16:33:12

US3142137

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:22:24
User entered 'Yes (Y)'	Meghan York (b) (4)	21 Oct 2020 16:33:17

US3142137

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:08
User entered 'I'	System	21 Oct 2020 16:33:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 64'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-10-10T11:40:04', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4eadb267-c7b5-4670-a405-ba1a776e42cf'	System	10 Oct 2020 17:40:14
User entered 'No (N)'	System	10 Oct 2020 17:40:14

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-10-10T11:40:07', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4eadb267-c7b5-4670-a405-ba1a776e42cf'	System	10 Oct 2020 17:40:14
User entered 'No (N)'	System	10 Oct 2020 17:40:14

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-10-10T11:40:11', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4eadb267-c7b5-4670-a405-ba1a776e42cf'	System	10 Oct 2020 17:40:14
User entered '10 Oct 2020 11:40:11'	System	10 Oct 2020 17:40:14

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 71'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-10-13T08:48:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'de61e32d-f7c9-4931-95df-73a6e7836800'	System	13 Oct 2020 14:48:42
User entered 'No (N)'	System	13 Oct 2020 14:48:42

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-10-13T08:48:34', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'de61e32d-f7c9-4931-95df-73a6e7836800'	System	13 Oct 2020 14:48:42
User entered 'No (N)'	System	13 Oct 2020 14:48:42

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-10-13T08:48:38', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'de61e32d-f7c9-4931-95df-73a6e7836800'	System	13 Oct 2020 14:48:42
User entered '13 Oct 2020 08:48:38'	System	13 Oct 2020 14:48:42

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 78'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-10-22T12:07:38', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'ebf519f9-2205-40d5-8519-9a939c563058'	System	22 Oct 2020 18:07:47
User entered 'No (N)'	System	22 Oct 2020 18:07:47

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-10-22T12:07:41', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'ebf519f9-2205-40d5-8519-9a939c563058'	System	22 Oct 2020 18:07:47
User entered 'No (N)'	System	22 Oct 2020 18:07:47

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-10-22T12:07:45', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'ebf519f9-2205-40d5-8519-9a939c563058'	System	22 Oct 2020 18:07:47
User entered '22 Oct 2020 12:07:45'	System	22 Oct 2020 18:07:47

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 92'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-11-05T17:28:54', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6a5408c-cbee-4a14-8076-8acd3b905564'	System	06 Nov 2020 00:29:05
User entered 'No (N)'	System	06 Nov 2020 00:29:05

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-11-05T17:28:57', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6a5408c-cbee-4a14-8076-8acd3b905564'	System	06 Nov 2020 00:29:05
User entered 'No (N)'	System	06 Nov 2020 00:29:05

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-11-05T17:29:02', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e6a5408c-cbee-4a14-8076-8acd3b905564' User entered '05 Nov 2020 17:29:02'	System	06 Nov 2020 00:29:05
	System	06 Nov 2020 00:29:05

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 99'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Please 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 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Please 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 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Please 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 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32

US3142137

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:03:32
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered 'Day 106'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-11-17T07:18:02', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'bee2784e-c71b-43e3-8e03-6e91cf8077df'	System	17 Nov 2020 14:19:14
User entered 'Yes (Y)'	System	17 Nov 2020 14:19:14

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-11-17T07:18:13', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'bee2784e-c71b-43e3-8e03-6e91cf8077df'	System	17 Nov 2020 14:19:14
User entered 'No (N)'	System	17 Nov 2020 14:19:14

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-11-17T07:18:20', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'bee2784e-c71b-43e3-8e03-6e91cf8077df'	System	17 Nov 2020 14:19:14
User entered 'No (N)'	System	17 Nov 2020 14:19:14

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-11-17T07:19:04', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'bee2784e-c71b-43e3-8e03-6e91cf8077df'	System	17 Nov 2020 14:19:14
User entered 'No (N)'	System	17 Nov 2020 14:19:14

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-11-17T07:19:11', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'bee2784e-c71b-43e3-8e03-6e91cf8077df' User entered '17 Nov 2020 07:19:11'	System	17 Nov 2020 14:19:14
	System	17 Nov 2020 14:19:14

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 20:50:17

US3142137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:36
Data entry locked.	System	06 Aug 2020 20:50:17
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 20:50:17

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2020-11-21T10:47:40', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '64c6817d-44e8-44b9-b5db-9cb86a674abc'	System	21 Nov 2020 17:48:00
User entered 'No (N)'	System	21 Nov 2020 17:48:00

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2020-11-21T10:47:51', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '64c6817d-44e8-44b9-b5db-9cb86a674abc'	System	21 Nov 2020 17:48:00
User entered 'No (N)'	System	21 Nov 2020 17:48:00

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-11-21T10:47:56', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '64c6817d-44e8-44b9-b5db-9cb86a674abc'	System	21 Nov 2020 17:48:00
User entered '21 Nov 2020 10:47:56'	System	21 Nov 2020 17:48:00

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2020-11-28T08:16:54', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a11a40d-1d20-46f0-937a-7c3b5b85bd08'	System	28 Nov 2020 15:17:07
User entered 'No (N)'	System	28 Nov 2020 15:17:07

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2020-11-28T08:16:57', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a11a40d-1d20-46f0-937a-7c3b5b85bd08'	System	28 Nov 2020 15:17:07
User entered 'No (N)'	System	28 Nov 2020 15:17:07

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-11-28T08:17:04', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '4a11a40d-1d20-46f0-937a-7c3b5b85bd08'	System	28 Nov 2020 15:17:07
User entered '28 Nov 2020 08:17:04'	System	28 Nov 2020 15:17:07

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2020-12-05T07:27:21', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8f5ae8ed-9c13-4fec-99e2-4c4e697d69b0'	System	05 Dec 2020 14:27:35
User entered 'No (N)'	System	05 Dec 2020 14:27:35

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2020-12-05T07:27:27', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8f5ae8ed-9c13-4fec-99e2-4c4e697d69b0'	System	05 Dec 2020 14:27:35
User entered 'No (N)'	System	05 Dec 2020 14:27:35

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-12-05T07:27:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8f5ae8ed-9c13-4fec-99e2-4c4e697d69b0'	System	05 Dec 2020 14:27:35
User entered '05 Dec 2020 07:27:31'	System	05 Dec 2020 14:27:35

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2020-12-23T09:54:43', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'baa30e88-9688-48e0-867b-e1ab1731bb58'	System	23 Dec 2020 16:55:30
User entered 'No (N)'	System	23 Dec 2020 16:55:30

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2020-12-23T09:55:23', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'baa30e88-9688-48e0-867b-e1ab1731bb58'	System	23 Dec 2020 16:55:30
User entered 'No (N)'	System	23 Dec 2020 16:55:30

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-12-23T09:55:27', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'baa30e88-9688-48e0-867b-e1ab1731bb58'	System	23 Dec 2020 16:55:30
User entered '23 Dec 2020 09:55:27'	System	23 Dec 2020 16:55:30

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2020-12-26T09:13:25', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '0c99b014-67cc-46df-ad05-e6d4da79a2d4'	System	26 Dec 2020 16:13:34
User entered 'No (N)'	System	26 Dec 2020 16:13:34

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2020-12-26T09:13:28', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '0c99b014-67cc-46df-ad05-e6d4da79a2d4'	System	26 Dec 2020 16:13:34
User entered 'No (N)'	System	26 Dec 2020 16:13:34

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2020-12-26T09:13:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '0c99b014-67cc-46df-ad05-e6d4da79a2d4'	System	26 Dec 2020 16:13:34
User entered '26 Dec 2020 09:13:31'	System	26 Dec 2020 16:13:34

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-01-02T08:52:34', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e8477147-b88f-49ee-842c-15a73077bf30'	System	02 Jan 2021 15:52:48
User entered 'No (N)'	System	02 Jan 2021 15:52:48

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-01-02T08:52:38', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e8477147-b88f-49ee-842c-15a73077bf30'	System	02 Jan 2021 15:52:48
User entered 'No (N)'	System	02 Jan 2021 15:52:48

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-01-02T08:52:42', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'e8477147-b88f-49ee-842c-15a73077bf30' User entered '02 Jan 2021 08:52:42'	System	02 Jan 2021 15:52:48
	System	02 Jan 2021 15:52:48

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-01-09T07:20:28', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b45b2b68-e833-47e1-8ccc-21eaa562feb4'	System	09 Jan 2021 14:20:41
User entered 'No (N)'	System	09 Jan 2021 14:20:41

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-01-09T07:20:33', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b45b2b68-e833-47e1-8ccc-21eaa562feb4'	System	09 Jan 2021 14:20:41
User entered 'No (N)'	System	09 Jan 2021 14:20:41

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-01-09T07:20:38', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b45b2b68-e833-47e1-8ccc-21eaa562feb4'	System	09 Jan 2021 14:20:41
User entered '09 Jan 2021 07:20:38'	System	09 Jan 2021 14:20:41

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-01-16T07:32:19', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8f3f56c6-7900-4533-b769-df2cde7f7e2d'	System	16 Jan 2021 14:32:33
User entered 'No (N)'	System	16 Jan 2021 14:32:33

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-01-16T07:32:27', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8f3f56c6-7900-4533-b769-df2cde7f7e2d'	System	16 Jan 2021 14:32:33
User entered 'No (N)'	System	16 Jan 2021 14:32:33

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-01-16T07:32:31', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '8f3f56c6-7900-4533-b769-df2cde7f7e2d'	System	16 Jan 2021 14:32:33
User entered '16 Jan 2021 07:32:31'	System	16 Jan 2021 14:32:33

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-01-23T08:17:04', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '83e0cc7d-26e2-4adc-a677-14cffa168ddb'	System	23 Jan 2021 15:17:20
User entered 'No (N)'	System	23 Jan 2021 15:17:20

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-01-23T08:17:09', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '83e0cc7d-26e2-4adc-a677-14cffa168ddb'	System	23 Jan 2021 15:17:20
User entered 'No (N)'	System	23 Jan 2021 15:17:20

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-01-23T08:17:13', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '83e0cc7d-26e2-4adc-a677-14cffa168ddb' User entered '23 Jan 2021 08:17:13'	System	23 Jan 2021 15:17:20

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-01-30T08:10:09', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c7c582b7-7bb8-4653-b61e-b3e38a3437c8'	System	30 Jan 2021 15:10:22
User entered 'No (N)'	System	30 Jan 2021 15:10:22

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-01-30T08:10:12', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c7c582b7-7bb8-4653-b61e-b3e38a3437c8'	System	30 Jan 2021 15:10:22
User entered 'No (N)'	System	30 Jan 2021 15:10:22

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-01-30T08:10:15', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c7c582b7-7bb8-4653-b61e-b3e38a3437c8'	System	30 Jan 2021 15:10:22
User entered '30 Jan 2021 08:10:15'	System	30 Jan 2021 15:10:22

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-02-06T21:26:35', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b86dd952-a694-49e6-b62c-e796176a5226'	System	07 Feb 2021 04:26:47
User entered 'No (N)'	System	07 Feb 2021 04:26:47

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-02-06T21:26:38', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b86dd952-a694-49e6-b62c-e796176a5226'	System	07 Feb 2021 04:26:47
User entered 'No (N)'	System	07 Feb 2021 04:26:47

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-02-06T21:26:41', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b86dd952-a694-49e6-b62c-e796176a5226'	System	07 Feb 2021 04:26:47
User entered '06 Feb 2021 21:26:41'	System	07 Feb 2021 04:26:47

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-02-13T07:39:51', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '08896919-c1bd-4011-b5d9-a6c772d19735'	System	13 Feb 2021 14:40:32
User entered 'Yes (Y)'	System	13 Feb 2021 14:40:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-02-13T07:39:54', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '08896919-c1bd-4011-b5d9-a6c772d19735'	System	13 Feb 2021 14:40:32
User entered 'No (N)'	System	13 Feb 2021 14:40:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-02-13T07:39:57', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '08896919-c1bd-4011-b5d9-a6c772d19735'	System	13 Feb 2021 14:40:32
User entered 'No (N)'	System	13 Feb 2021 14:40:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-02-13T07:40:05', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '08896919-c1bd-4011-b5d9-a6c772d19735'	System	13 Feb 2021 14:40:32
User entered 'Yes (Y)'	System	13 Feb 2021 14:40:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-02-13T07:40:14', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '08896919-c1bd-4011-b5d9-a6c772d19735'	System	13 Feb 2021 14:40:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 14:40:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-02-13T07:40:21', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '08896919-c1bd-4011-b5d9-a6c772d19735'	System	13 Feb 2021 14:40:32
User entered '13 Feb 2021 07:40:21'	System	13 Feb 2021 14:40:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-02-20T07:32:08', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3d4ad5ca-6282-44a3-911f-c43d99624812'	System	20 Feb 2021 14:32:19
User entered 'No (N)'	System	20 Feb 2021 14:32:19

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-02-20T07:32:12', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3d4ad5ca-6282-44a3-911f-c43d99624812'	System	20 Feb 2021 14:32:19
User entered 'No (N)'	System	20 Feb 2021 14:32:19

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-02-20T07:32:16', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3d4ad5ca-6282-44a3-911f-c43d99624812'	System	20 Feb 2021 14:32:19
User entered '20 Feb 2021 07:32:16'	System	20 Feb 2021 14:32:19

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-02-27T07:43:50-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '41e36a03-f09c-4843-9409-ef08b6abcd61'	System	27 Feb 2021 14:43:59
User entered 'No (N)'	System	27 Feb 2021 14:43:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-02-27T07:43:53-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '41e36a03-f09c-4843-9409-ef08b6abcd61'	System	27 Feb 2021 14:43:59
User entered 'No (N)'	System	27 Feb 2021 14:43:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-02-27T07:43:57-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '41e36a03-f09c-4843-9409-ef08b6abcd61'	System	27 Feb 2021 14:43:59
User entered '27 Feb 2021 07:43:57'	System	27 Feb 2021 14:43:59

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-03-09T12:46:31-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '78e415b8-a563-454c-8ce1-214f20007e74'	System	09 Mar 2021 19:46:41
User entered 'No (N)'	System	09 Mar 2021 19:46:41

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-03-09T12:46:35-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '78e415b8-a563-454c-8ce1-214f20007e74'	System	09 Mar 2021 19:46:41
User entered 'No (N)'	System	09 Mar 2021 19:46:41

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-03-09T12:46:39-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '78e415b8-a563-454c-8ce1-214f20007e74' User entered '09 Mar 2021 12:46:39'	System	09 Mar 2021 19:46:41
	System	09 Mar 2021 19:46:41

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-03-13T08:33:43-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'd2639523-8591-44db-b6e9-c44942afdab0'	System	13 Mar 2021 15:33:51
User entered 'No (N)'	System	13 Mar 2021 15:33:51

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-03-13T08:33:46-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'd2639523-8591-44db-b6e9-c44942afdab0'	System	13 Mar 2021 15:33:51
User entered 'No (N)'	System	13 Mar 2021 15:33:51

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-03-13T08:33:49-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'd2639523-8591-44db-b6e9-c44942afdab0'	System	13 Mar 2021 15:33:51
User entered '13 Mar 2021 08:33:49'	System	13 Mar 2021 15:33:51

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-03-20T07:35:53-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'a7688681-9d26-411e-8ed7-d7693bc5f910'	System	20 Mar 2021 13:36:07
User entered 'No (N)'	System	20 Mar 2021 13:36:07

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-03-20T07:35:57-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'a7688681-9d26-411e-8ed7-d7693bc5f910'	System	20 Mar 2021 13:36:07
User entered 'No (N)'	System	20 Mar 2021 13:36:07

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-03-20T07:36:00-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'a7688681-9d26-411e-8ed7-d7693bc5f910'	System	20 Mar 2021 13:36:07
User entered '20 Mar 2021 07:36:00'	System	20 Mar 2021 13:36:07

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-03-27T01:39:10-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c9631200-c8a4-45e5-8e6f-a993a4083267'	System	27 Mar 2021 07:39:23
User entered 'No (N)'	System	27 Mar 2021 07:39:23

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-03-27T01:39:13-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c9631200-c8a4-45e5-8e6f-a993a4083267'	System	27 Mar 2021 07:39:23
User entered 'No (N)'	System	27 Mar 2021 07:39:23

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-03-27T01:39:17-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'c9631200-c8a4-45e5-8e6f-a993a4083267'	System	27 Mar 2021 07:39:23
User entered '27 Mar 2021 01:39:17'	System	27 Mar 2021 07:39:23

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-04-03T07:34:18-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b5edfa53-1bd1-4251-b401-d7d048e5e35c'	System	03 Apr 2021 13:34:33
User entered 'No (N)'	System	03 Apr 2021 13:34:33

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-04-03T07:34:22-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b5edfa53-1bd1-4251-b401-d7d048e5e35c'	System	03 Apr 2021 13:34:33
User entered 'No (N)'	System	03 Apr 2021 13:34:33

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-04-03T07:34:29-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'b5edfa53-1bd1-4251-b401-d7d048e5e35c'	System	03 Apr 2021 13:34:33
User entered '03 Apr 2021 07:34:29'	System	03 Apr 2021 13:34:33

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-04-10T07:28:15-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3cd9d41d-0580-45c1-b3fb-8239ffcf4a1a'	System	10 Apr 2021 13:28:26
User entered 'No (N)'	System	10 Apr 2021 13:28:26

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-04-10T07:28:18-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3cd9d41d-0580-45c1-b3fb-8239ffcf4a1a'	System	10 Apr 2021 13:28:26
User entered 'No (N)'	System	10 Apr 2021 13:28:26

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-04-10T07:28:21-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '3cd9d41d-0580-45c1-b3fb-8239ffcf4a1a'	System	10 Apr 2021 13:28:26
User entered '10 Apr 2021 07:28:21'	System	10 Apr 2021 13:28:26

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-04-17T08:27:39-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dcf15fd7-a06e-46c9-aa12-e823b9ca0a2c' User entered 'No (N)'	System	17 Apr 2021 14:27:45
	System	17 Apr 2021 14:27:45

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-04-17T08:27:41-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dcf15fd7-a06e-46c9-aa12-e823b9ca0a2c'	System	17 Apr 2021 14:27:45
User entered 'No (N)'	System	17 Apr 2021 14:27:45

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-04-17T08:27:45-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'dcf15fd7-a06e-46c9-aa12-e823b9ca0a2c'	System	17 Apr 2021 14:27:45
User entered '17 Apr 2021 08:27:45'	System	17 Apr 2021 14:27:45

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-04-24T07:34:06-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '55715d7a-0d15-4359-95ef-855fa0effb40'	System	24 Apr 2021 13:34:22
User entered 'No (N)'	System	24 Apr 2021 13:34:22

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-04-24T07:34:11-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '55715d7a-0d15-4359-95ef-855fa0effb40'	System	24 Apr 2021 13:34:22
User entered 'No (N)'	System	24 Apr 2021 13:34:22

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-04-24T07:34:15-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '55715d7a-0d15-4359-95ef-855fa0effb40'	System	24 Apr 2021 13:34:22
User entered '24 Apr 2021 07:34:15'	System	24 Apr 2021 13:34:22

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[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 (c781a3eac09b65e5)', Time: '2021-05-01T06:24:47-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '08afc5a8-0d99-4915-a89e-8fe4ef2b3bde'	System	01 May 2021 12:25:00
User entered 'No (N)'	System	01 May 2021 12:25:00

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

Have you been exposed to someone with 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 (c781a3eac09b65e5)', Time: '2021-05-01T06:24:50-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '08afc5a8-0d99-4915-a89e-8fe4ef2b3bde'	System	01 May 2021 12:25:00
User entered 'No (N)'	System	01 May 2021 12:25:00

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-05-01T06:24:55-06:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: '08afc5a8-0d99-4915-a89e-8fe4ef2b3bde'	System	01 May 2021 12:25:00
User entered '01 May 2021 06:24:55'	System	01 May 2021 12:25:00

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 15:03:32

US3142137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:25:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:03:32
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 15:03:32

US3142137

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:25:34

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 12:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-02-27T07:44:09-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'ed3163ba-16d6-4069-b101-f690748427e6'	System	27 Feb 2021 14:44:19
User entered 'No (N)'	System	27 Feb 2021 14:44:19

US3142137

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:25:34

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c781a3eac09b65e5)', Time: '2021-02-27T07:44:17-07:00', User OID: 'PatientReportedOutcome (US3142137)', ODM File OID: 'ed3163ba-16d6-4069-b101-f690748427e6' User entered '27 Feb 2021 07:44:17'	System	27 Feb 2021 14:44:19
	System	27 Feb 2021 14:44:19

US3142137

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:25:44
User entered 'Yes (Y)'	Jami Wagner (b) (4)	06 Nov 2020 16:53:27

US3142137

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User closed query 'Please make correction to date on source documents,' (Site from CRA).	(b) (4)	31 Mar 2021 19:36:11
Query 'Please make correction to date on source documents,' answered with 'done ' (Site from CRA).	Jill York (b) (4)	24 Mar 2021 15:35:28
User opened query 'Please make correction to date on source documents,' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:48:06
DataPoint Verified.		01 Mar 2021 19:25:42
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		16 Nov 2020 17:25:14
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'information is correct ' (Site from System).	Meghan York (b) (4)	10 Nov 2020 21:51:19
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	06 Nov 2020 16:53:27
User entered '5 Nov 2020'	Jami Wagner (b) (4)	06 Nov 2020 16:53:27

US3142137

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:25:37
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	06 Nov 2020 16:53:27

US3142137

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User closed query 'Please enter stop date for HCTZ on con med source log.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:36:30
Query 'Please enter stop date for HCTZ on con med source log.' answered with 'done ' (Site from CRA).	Jill York (b) (4)	24 Mar 2021 15:35:08
User opened query 'Please enter stop date for HCTZ on con med source log.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:28:07
DataPoint Verified.		01 Mar 2021 19:25:35
User closed query 'Per DM CLR: Comment = SUBJECT STOPPED TAKING HCTV MEDICATION ON 05NOV2020, however, the corresponding Conmed remains ongoing. Please reconcile and update as appropriate, otherwise clarify.' (Site from DM).		02 Dec 2020 19:09:30
Query 'Per DM CLR: Comment = SUBJECT STOPPED TAKING HCTV MEDICATION ON 05NOV2020, however, the corresponding Conmed remains ongoing. Please reconcile and update as appropriate, otherwise clarify.' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4)	01 Dec 2020 19:51:59
User opened query 'Per DM CLR: Comment = SUBJECT STOPPED TAKING HCTV MEDICATION ON 05NOV2020, however, the corresponding Conmed remains ongoing. Please reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 11:59:51
User entered 'subject stopped taking HCTV medication on 05NOV2020'	Jami Wagner (b) (4)	06 Nov 2020 16:53:27

US3142137

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:36:38
User entered 'Yes (Y)'	Jami Wagner (b) (4)	06 Nov 2020 16:53:34

US3142137

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:06
User entered 'I'	System	06 Nov 2020 16:53:34

US3142137

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User closed query 'Please enter stop date for HCTZ and dose change for Losartan as per source docs if agreed.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:44:57
Query 'Please enter stop date for HCTZ and dose change for Losartan as per source docs if agreed.' answered with 'done ' (Site from CRA).	Jill York (b) (4)	01 Feb 2021 20:50:43
User opened query 'Please enter stop date for HCTZ and dose change for Losartan as per source docs if agreed.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 21:30:05
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:27:45
User entered 'Yes (Y)'	Jami Wagner (b) (4)	10 Dec 2020 17:53:22

US3142137

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:27:45
User entered '9 Dec 2020'	Jami Wagner (b) (4)	10 Dec 2020 17:53:22

US3142137

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:27:45
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	10 Dec 2020 17:53:22

US3142137

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:27:45
User entered empty.	Jami Wagner (b) (4)	10 Dec 2020 17:53:22

US3142137

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:37:13
User entered 'Yes (Y)'	Jami Wagner (b) (4)	10 Dec 2020 17:53:43

US3142137

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User entered 'I'	System	10 Dec 2020 17:53:43

US3142137

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 20:41:23
User entered 'Yes (Y)'	Jami Wagner (b) (4)	04 Jan 2021 22:06:38

US3142137

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 20:41:23
User entered '4 Jan 2021'	Jami Wagner (b) (4)	04 Jan 2021 22:06:38

US3142137

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 20:41:23
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	04 Jan 2021 22:06:38

US3142137

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 20:41:23
User entered empty.	Jami Wagner (b) (4)	04 Jan 2021 22:06:38

US3142137

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:45:44
User entered 'Yes (Y)'	Jami Wagner (b) (4)	04 Jan 2021 22:06:48

US3142137

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User entered 'I'	System	04 Jan 2021 22:06:48

US3142137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
DataPoint Verified.		19 Apr 2021 18:42:52
User closed query 'Please file source documentation for this call in subject binder.' (Site from CRA).		19 Apr 2021 18:42:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
	(b) (4)	
Query 'Please file source documentation for this call in subject binder.' answered with 'filed under phone calls in subject binder' (Site from CRA).	Jill York (b) (4)	14 Apr 2021 19:19:44
User opened query 'Please file source documentation for this call in subject binder.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:39:16
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	03 Mar 2021 23:58:07
	(b) (4)	

US3142137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
DataPoint Verified.		19 Apr 2021 18:42:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User entered '02 Feb 2021'	(b) (4)	
	Lisa Jackson (b) (4)	03 Mar 2021 23:58:07
	(b) (4)	

US3142137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
DataPoint Verified.		19 Apr 2021 18:42:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	03 Mar 2021 23:58:07

US3142137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
DataPoint Verified.		19 Apr 2021 18:42:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User entered empty.	(b) (4) Lisa Jackson (b) (4) (b) (4)	03 Mar 2021 23:58:07

US3142137

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
DataPoint Verified.		19 Apr 2021 18:43:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User entered 'Yes (Y)'	(b) (4)	
	Lisa Jackson (b) (4)	03 Mar 2021 23:58:22
	(b) (4)	

US3142137

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:15
User entered 'I'	System	03 Mar 2021 23:58:22

US3142137

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:50:10
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	31 Mar 2021 22:16:27

US3142137

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:50:14
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		02 Apr 2021 07:28:39
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'data is as documented' (Site from System).	Lisa Jackson (b) (4) (b) (4)	31 Mar 2021 22:17:00
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	31 Mar 2021 22:16:27
User entered '16 Feb 2021'	Lisa Jackson (b) (4) (b) (4)	31 Mar 2021 22:16:27

US3142137

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[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 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:50:14
User entered 'Clinic (Clinic)'	Lisa Jackson (b) (4)	31 Mar 2021 22:16:27

US3142137

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User entered 'VISIT4'	System	31 Mar 2021 22:16:27

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:37:34
User entered 'No (N)'	Lisa Jackson (b) (4)	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:37:34
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:37:34
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User entered empty.	System	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:37:34
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:37:34
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:37:34
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:37:34
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User entered empty.	System	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:37:34
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User entered empty.	System	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:37:34
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User entered empty.	System	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:37:34
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User entered empty.	System	31 Mar 2021 22:17:18

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58

US3142137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58

US3142137

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:44:25
User entered 'No (N)'	Lisa Jackson (b) (4)	31 Mar 2021 22:17:25

US3142137

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:44:25
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 22:17:25

US3142137

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:51
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	31 Mar 2021 22:20:29

US3142137

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:51
User entered '16 Feb 2021'	Lisa Jackson (b) (4)	31 Mar 2021 22:20:29

US3142137

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:51
User entered '09:06'	Lisa Jackson (b) (4)	31 Mar 2021 22:20:29

US3142137

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User entered '16 Feb 2021 09:06'	System	31 Mar 2021 22:20:29

US3142137

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:45:56
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	31 Mar 2021 22:20:35

US3142137

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:58
User entered 'I'	System	31 Mar 2021 22:20:35

US3142137

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
	(b) (4)	
User entered 'Yes (Y)'	Jill York (b) (4)	06 Apr 2021 17:15:38

US3142137

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
	(b) (4)	
User entered '2 Apr 2021'	Jill York (b) (4)	06 Apr 2021 17:15:38

US3142137

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jill York (b) (4)	06 Apr 2021 17:15:38

US3142137

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
User entered empty.	(b) (4) Jill York (b) (4)	06 Apr 2021 17:15:38

US3142137

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

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:39:30
User entered 'Yes (Y)'	Meghan York (b) (4)	19 Jan 2021 16:25:14

US3142137

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

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:39:30
User entered '18 Jan 2021'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:25:14

US3142137

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

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:39:30
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	19 Jan 2021 16:25:14

US3142137

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

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 16:25:14

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:39:52
User entered '18 Jan 2021'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:25:42

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:30
User entered '0'	Jami Wagner (b) (4)	09 Apr 2021 17:51:20
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:45:39

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:39:52
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:25:42

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:07:46
		14 Apr 2021 17:10:33
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'data has been corrected' (Site from DM).	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 17:51:41
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 17:51:20
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	09 Apr 2021 17:13:01
	System	06 Mar 2021 11:45:39

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:39:52
User entered '18 Jan 2021'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:25:42

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:39:52
User entered 'Placebo (Placebo)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:25:42

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:39:52
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:33:59
User entered 'Placebo (Placebo)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:25:42

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:39:52
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:33:59
User entered 'Placebo (Placebo)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:25:42

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:39:52
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:25:42

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered '1'	System	19 Jan 2021 16:25:42

US3142137

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

Form: Unblinding

Generated On: 09 Jun 2021 15:25:34

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'I'	System	19 Jan 2021 16:25:42

US3142137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered missing code ND - Not Done.	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered missing code ND - Not Done.	Meghan York (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered empty.	System	19 Jan 2021 16:27:58
DataPoint set to visible.	System	19 Jan 2021 16:25:42

US3142137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered missing code ND - Not Done.	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered missing code ND - Not Done.	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered empty.	System	19 Jan 2021 16:27:58
DataPoint set to visible.	System	19 Jan 2021 16:25:42

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '18 Jan 2021'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '15:37'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered '18 Jan 2021 15:37'	System	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '97.6' F	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered 'Other (Other)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered 'temporal'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '81'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'bpm'	System	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '15'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'breaths/min'	System	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '142'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'mmHg'	System	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '91'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'mmHg'	System	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered missing code ND - Not Done.	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered missing code ND - Not Done.	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:25:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered empty.	System	19 Jan 2021 16:27:58
DataPoint set to visible.	System	19 Jan 2021 16:25:42

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '18 Jan 2021'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '16:32'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered '18 Jan 2021 16:32'	System	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '97.5' F	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered 'Other (Other)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered 'temporal'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '72'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'bpm'	System	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '12'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'breaths/min'	System	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '132'	Meghan York (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'mmHg'	System	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:40:42
User entered '78'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:27:58

US3142137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'mmHg'	System	19 Jan 2021 16:27:58

US3142137

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:04
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:28:09

US3142137

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:42:06
User entered '18 Jan 2021'	Meghan York (b) (4)	19 Jan 2021 16:28:09

US3142137

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

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:45
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	19 Jan 2021 16:28:48
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	19 Jan 2021 16:28:48
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	19 Jan 2021 16:28:38
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:28:38

US3142137

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

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:45
User entered empty.	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:28:38

US3142137

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

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:45
User entered empty.	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:28:38

US3142137

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

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'mRNA-1273'	System	19 Jan 2021 16:28:38
DataPoint set to visible.	System	19 Jan 2021 16:25:42

US3142137

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

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:45
User entered '18 Jan 2021'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:28:38

US3142137

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

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:45
User entered '16:02'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:28:38

US3142137

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

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered '18 Jan 2021 16:02'	System	19 Jan 2021 16:28:38

US3142137

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

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:42:45
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Meghan York (b) (4)	19 Jan 2021 16:28:48
User entered empty.	Meghan York (b) (4)	19 Jan 2021 16:28:38

US3142137

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

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
DataPoint Verified.		31 Mar 2021 19:42:45
User entered 'ONCE'	System	19 Jan 2021 16:28:38

US3142137

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

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 16:28:38

US3142137

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:43:29
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:29:12

US3142137

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:43:29
User entered '18 Jan 2021'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:29:12

US3142137

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:43:29
User entered '14:53'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:29:12

US3142137

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered '18 Jan 2021 14:53'	System	19 Jan 2021 16:29:12

US3142137

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:43:38
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:29:30

US3142137

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:25:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:43:38
User entered '18 Jan 2021'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:29:30

US3142137

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:25:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:43:38
User entered '14:58'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:29:30

US3142137

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:25:34

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered '18 Jan 2021 14:58'	System	19 Jan 2021 16:29:30

US3142137

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

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:43:43
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	19 Jan 2021 16:29:35

US3142137

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

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'I'	System	19 Jan 2021 16:29:35

US3142137

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:44:46
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Feb 2021 22:41:28

US3142137

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:44:46
User entered '25 Jan 2021'	Jami Wagner (b) (4)	01 Feb 2021 22:41:28

US3142137

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:44:46
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:41:28

US3142137

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:44:46
User closed query 'Per DM CLR: Review specified comment, WHOLE ARM PAIN AND SWELLING . Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).		09 Mar 2021 09:54:29
Query 'Per DM CLR: Review specified comment, WHOLE ARM PAIN AND SWELLING . Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' answered with 'not considered an AE' (Site from DM).	Jill York (b) (4)	01 Mar 2021 18:42:50
User opened query 'Per DM CLR: Review specified comment, WHOLE ARM PAIN AND SWELLING . Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:31:52
Query 'Per DM CLR: Please review if WHOLE ARM PAIN AND SWELLING are considered an AE event and should be recorded in AE ecrf. Review and update as appropriate. ' canceled (Site from DM).		01 Mar 2021 06:31:48
User opened query 'Per DM CLR: Please review if WHOLE ARM PAIN AND SWELLING are considered an AE event and should be recorded in AE ecrf. Review and update as appropriate. ' (Site from DM).		25 Feb 2021 22:44:47
User entered 'whole arm hurt for 2 days following vaccine still swelled for 2 days. Pain only when touched.'	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:41:28

US3142137

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:44:58
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Feb 2021 22:41:34

US3142137

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'I'	System	01 Feb 2021 22:41:34

US3142137

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'I'	System	01 Feb 2021 22:41:34
DataPoint set to visible.	System	01 Feb 2021 22:41:34

US3142137

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:47:31
User entered 'Yes (Y)'	Jill York (b) (4)	16 Feb 2021 18:29:03

US3142137

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:47:31
User entered '16 Feb 2021'	Jill York (b) (4)	16 Feb 2021 18:29:03

US3142137

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:47:31
User entered 'Clinic (Clinic)'	Jill York (b) (4)	16 Feb 2021 18:29:03

US3142137

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'OLD29'	System	16 Feb 2021 18:29:03

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User accepted default value 'Pre-Dose (PREDOSE)'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered 'Yes (Y)'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '16 Feb 2021'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '9:43'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered '16 Feb 2021 9:43'	System	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '98.3' F	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered 'Other (Other)'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered 'temporal'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '77'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'bpm'	System	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '14'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'breaths/min'	System	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '112'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'mmHg'	System	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '75'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:25:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'mmHg'	System	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User accepted default value 'Post-Dose (POSTDOSE)'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered 'Yes (Y)'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '16 Feb 2021'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '11:19'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered '16 Feb 2021 11:19'	System	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '97.5' F	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered 'Other (Other)'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered 'temporal'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '73'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'bpm'	System	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '12'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'breaths/min'	System	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '113'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'mmHg'	System	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:28
User entered '74'	Jill York (b) (4)	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'mmHg'	System	16 Feb 2021 18:35:55

US3142137

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:39
User entered 'Yes (Y)'	Jill York (b) (4)	16 Feb 2021 18:36:06

US3142137

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:48:39
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Feb 2021 18:36:12
User entered '16 Feb 2021' reason for change: Data Entry Error	Jill York (b) (4)	16 Feb 2021 18:36:12
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Feb 2021 18:36:06
User entered '15 Feb 2021'	Jill York (b) (4)	16 Feb 2021 18:36:06

US3142137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:49:02
User entered 'Yes (Y)'	Jill York (b) (4)	16 Feb 2021 18:36:56

US3142137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:49:02
User entered empty.	Jill York (b) (4)	16 Feb 2021 18:36:56

US3142137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:49:02
User entered empty.	Jill York (b) (4)	16 Feb 2021 18:36:56

US3142137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'mRNA-1273'	System	16 Feb 2021 18:36:56
DataPoint set to visible.	System	01 Feb 2021 22:41:34

US3142137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:49:02
User entered '16 Feb 2021'	Jill York (b) (4)	16 Feb 2021 18:36:56

US3142137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:49:02
User entered '10:49'	Jill York (b) (4)	16 Feb 2021 18:36:56

US3142137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered '16 Feb 2021 10:49'	System	16 Feb 2021 18:36:56

US3142137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:49:02
User entered 'Left Arm (LEFT ARM)'	Jill York (b) (4)	16 Feb 2021 18:36:56

US3142137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
DataPoint Verified.		31 Mar 2021 19:49:02
User entered 'ONCE'	System	16 Feb 2021 18:36:56

US3142137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:25:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 18:36:56

US3142137

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:49:08
User entered 'Yes (Y)'	Jill York (b) (4)	16 Feb 2021 18:37:03

US3142137

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'I'	System	16 Feb 2021 18:37:03

US3142137

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:07:21
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	31 Mar 2021 22:30:01

US3142137

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:07:21
User entered '24 Feb 2021'	Lisa Jackson (b) (4)	31 Mar 2021 22:30:01

US3142137

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:07:21
User entered 'Contact Made (CONTACT MADE)'	Lisa Jackson (b) (4)	31 Mar 2021 22:30:01

US3142137

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:25:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:07:21
User entered empty.	Lisa Jackson (b) (4) (b) (4)	31 Mar 2021 22:30:01

US3142137

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:07:57
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	31 Mar 2021 22:30:07

US3142137

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:25:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:18
User entered 'I'	System	31 Mar 2021 22:30:07

US3142137

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:04:53
User entered 'Yes (Y)'	Jill York (b) (4)	01 Apr 2021 21:56:50

US3142137

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:04:53
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).		02 Apr 2021 07:32:42
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'date is correct' (Site from System).	Jill York (b) (4)	01 Apr 2021 21:56:59
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Apr 2021 21:56:50
User entered '1 Apr 2021'	Jill York (b) (4)	01 Apr 2021 21:56:50

US3142137

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:04:53
User entered 'Clinic (Clinic)'	Jill York (b) (4)	01 Apr 2021 21:56:50

US3142137

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:25:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	01 Apr 2021 21:56:50

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:00:22
User entered 'Yes (Y)'	Jill York (b) (4)	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:00:22
User entered '1 Apr 2021'	Jill York (b) (4)	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:00:22
User entered '09:28'	Jill York (b) (4)	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Apr 2021 09:28'	System	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:00:22
User entered '97.7' F	Jill York (b) (4)	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:00:22
User entered 'Other (Other)'	Jill York (b) (4)	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:00:22
User entered 'temporal'	Jill York (b) (4)	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:00:22
User entered '70'	Jill York (b) (4)	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:00:22
User entered '13'	Jill York (b) (4)	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:00:22
User entered '103'	Jill York (b) (4)	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:00:22
User entered '73'	Jill York (b) (4)	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:25:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 21:57:43

US3142137

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:06:04
User entered 'Yes (Y)'	Jill York (b) (4)	01 Apr 2021 21:57:52

US3142137

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:25:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:06:04
User entered '1 Apr 2021'	Jill York (b) (4)	01 Apr 2021 21:57:52

US3142137

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:09:53
User entered 'Yes (Y)'	Jill York (b) (4)	01 Apr 2021 21:58:06

US3142137

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:09:53
User entered '1 Apr 2021'	Jill York (b) (4)	01 Apr 2021 21:58:06

US3142137

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:09:53
User entered '10:11'	Jill York (b) (4)	01 Apr 2021 21:58:06

US3142137

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:25:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Apr 2021 10:11'	System	01 Apr 2021 21:58:06

US3142137

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:25:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:19
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:29
User closed query 'Per the V2 D29 source, subject reported having been newly diagnosed with kidney cancer. Please verify and ad AE to source and EDC.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 21:05:12
Query 'Per the V2 D29 source, subject reported having been newly diagnosed with kidney cancer. Please verify and ad AE to source and EDC.' answered with 'added' (Site from CRA).	Jill York (b) (4)	14 Apr 2021 19:16:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:54:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	01 Apr 2021 21:58:21
User opened query 'Per the V2 D29 source, subject reported having been newly diagnosed with kidney cancer. Please verify and ad AE to source and EDC.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:51:30
User entered 'No (N)'	Shelby Pickle (b) (4)	24 Mar 2021 17:08:15

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
Reviewed for Safety.		02 Apr 2021 13:22:03
Un-reviewed for Safety.		02 Apr 2021 13:22:00
Reviewed for Safety.		02 Apr 2021 13:21:53
Un-reviewed for Safety.		02 Apr 2021 13:21:47
Reviewed for Safety.		02 Apr 2021 13:21:16
User entered 'USA-US064-2021-mRNA-1273-P301000009'		02 Apr 2021 13:20:59
User entered 'New'		02 Apr 2021 13:20:59

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Adverse event](#)

Audit	User	Time (GMT)
User closed 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)	15 Apr 2021 19:30:23
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 'site has yet to review medical records. Will update ' (Site from Safety).	Jill York (b) (4)	14 Apr 2021 19:15:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User opened 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)	08 Apr 2021 15:17:00
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cancer, LLT: Kidney carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 10:39:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 10:39:16
Data point term sent to Coder	System	01 Apr 2021 22:12:17
User entered 'LEFT KIDNEY CARCINOMA' reason for change: Data Entry Error	Jill York (b) (4)	01 Apr 2021 22:11:43
Data point term sent to Coder	System	01 Apr 2021 22:10:15
User entered 'left kindey carcinoma'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'Yes (Y)'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'PER CDM: Response noted as YES, however both Relationship to IP and Relationship to Study Procedure are both recorded as NOT RELATED. Kindly review and update fields else clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:51:17
		21 Apr 2021 14:53:20
Query 'PER CDM: Response noted as YES, however both Relationship to IP and Relationship to Study Procedure are both recorded as NOT RELATED. Kindly review and update fields else clarify. ' answered with 'updated/corrected' (Site from DM). DataPoint Un-verified.	Jill York (b) (4)	20 Apr 2021 18:49:26
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	20 Apr 2021 18:49:12
User opened query 'PER CDM: Response noted as YES, however both Relationship to IP and Relationship to Study Procedure are both recorded as NOT RELATED. Kindly review and update fields else clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 11:11:57
		14 Apr 2021 16:55:58
User entered 'Yes (Y)'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'No (N)'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered '09 Feb 2021'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered empty.	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 22:10:21
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	01 Apr 2021 22:10:21
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 22:09:55
User entered 'Yes (Y)'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered '04 Mar 2021'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered empty.	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'Yes (Y)'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered '0'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered '0'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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)	15 Apr 2021 19:30:34
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		15 Apr 2021 19:30:32
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 'will update when site reviews records' (Site from Safety).	Jill York (b) (4)	14 Apr 2021 19:17:33
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'site has yet to review records. Will update' (Site from Safety).	Jill York (b) (4)	14 Apr 2021 19:17:11
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		08 Apr 2021 15:17:33

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Requires inpatient or prolongation of existing Hospitalization](#)

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)	08 Apr 2021 15:16:34
User entered 'I'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered '04 Mar 2021'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 12:48:26
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'site does not yet have records' (Site from Safety).	Jill York (b) (4)	20 Apr 2021 18:49:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 15:17:58
User entered '07 Mar 2021'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'No (N)'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered empty.	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered '0'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered '0'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered '0'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'Not Related (NOT RELATED)'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'Not Related (NOT RELATED)'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'None (NONE)'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered '0'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'I'	Jill York (b) (4)	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'I'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:55:58
User entered empty.	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 18:08:15
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. Please leave query open until information is available.' (Site from Safety).		21 Apr 2021 18:08:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).		21 Apr 2021 18:07:43
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. Please leave query open until information is available.' (Site from Safety).		21 Apr 2021 18:07:25
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. Please leave query open until information is available.' (Site from Safety).		21 Apr 2021 12:49:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 12:49:34
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).		21 Apr 2021 12:48:44
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. Please leave query open until information is available.' answered with 'site does not yet have records' (Site from Safety).	Jill York (b) (4)	20 Apr 2021 18:50:09
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. Please leave query open until information is available.' answered with 'site does not yet have records' (Site from Safety).	Jill York (b) (4)	20 Apr 2021 18:50:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[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. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' answered with 'site does not yet have records' (Site from Safety). 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. Please leave query open until information is available.' (Site from Safety).	Jill York (b) (4)	20 Apr 2021 18:49:58
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 19:31:08
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).		15 Apr 2021 19:29:50
DataPoint Verified.		15 Apr 2021 19:26:07
		14 Apr 2021 16:55:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS BEING FOLLOWED MEDICALLY AFTER A CAR ACCIDENT 25 JULY 2020. DURING THE COURSE OF FOLLOW UP FOR A PRESTUDY ISSUE OF BACK PAIN RELATED TO THE CAR ACCIDENT, AN MRI DONE 09 FEB 2021 FOUND A LEFT KIDNEY TUMOR SUSPICIOUS FOR KIDNEY CARCINOMA. SUBJECT WAS SCHEDULED FOR A LEFT RADICAL NEPHRECTOMY ON 04 MAR 2021. SUBJECT HOSPITALIZED FOR A LEFT RADICAL NEPHRECTOMY ON 04 MARCH 2021 AND DISCHARGED HOME 07 MARCH 2021. SUBJECT'S LEFT KIDNEY WAS REMOVED 04 March 2021 AND PER SUBJECT THE MARGINS WERE "CLEAN" AND THE CANCER WAS COMPLETELY REMOVED. NO RADIATION OR CHEMOTHERAPY IS PLANNED. SUBJECT WILL BE FOLLOWED BY PCP WITH A CHEST X-RAY AND MRI OR CT SCAN EVERY 6 MONTHS. SUBJECT'S HOSPITALIZATION RECORDS WILL BE REQUESTED.' reason for change: Data Entry Error	Jill York (b) (4)	01 Apr 2021 22:11:43
User entered 'Subject was being followed medically after a car accident 25 July 2020. During the course of follow up for a prestudy issue of back pain related to the car accident, an MRI done 09 Feb 2021 found a left kidney tumor suspicious for kidney carcinoma. Subject was scheduled for a left radical nephrectomy on 04 Mar 2021. Subject hospitalized for a left radical nephrectomy on 04 March 2021 and discharged home 07 March 2021. Subject's left kidney was removed and per subject the margins were "clean" and the cancer was completely removed. No radiation or chemotherapy is planned. Subject will be followed by PCP with a chest x-ray and MRI or CT scan every 6 months. Subject's hospitalization records will be requested.'	Jill York (b) (4)	01 Apr 2021 22:09:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 22:09:55

US3142137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:25:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 22:09:55

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:19
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:29
User closed query '(QUERY FOR AE PAGE) Per DM CLR: Per Day 194 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 08:09:39
Query '(QUERY FOR AE PAGE) Per DM CLR: Per Day 194 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'AE of kidney cancer has been added' (Site from DM).	Jill York (b) (4)	14 Apr 2021 19:18:55
User opened query '(QUERY FOR AE PAGE) Per DM CLR: Per Day 194 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 06:13:05
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:54:46
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:18:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 15:55:29
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: THYROID, PRODUCTSYNONYM: ARMOUR THYROID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Sep 2020 22:21:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Sep 2020 22:21:43
Data point term sent to Coder	System	04 Sep 2020 22:20:29
User entered 'armour thyroid'	Meghan York (b) (4)	04 Sep 2020 22:19:34
	(b) (4)	

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:55:30
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:55:40
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).		16 Oct 2020 14:05:25
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'This condition is now added to Med History ' (Site from DM).	Meghan York (b) (4) (b) (4)	14 Oct 2020 15:35:13
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:39:41
User entered 'hypothyroidism'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:01
User entered '30'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:03
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:04
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:06
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 15:56:08
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:19:34
	(b) (4)	

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:33
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:36
User entered 'UN UNK 1992'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:38
User entered '0'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:39
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:46
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:56:47
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 22:19:34

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 19:39:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 19:39:48
Data point term sent to Coder	System	27 Oct 2020 19:38:10
Coding entries removed.	Meghan York (b) (4)	27 Oct 2020 19:37:25
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 22:21:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 22:21:43
Data point term sent to Coder	System	04 Sep 2020 22:20:29
User entered 'claritin'	Meghan York (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:47:35
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).		02 Nov 2020 09:55:17
Query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	27 Oct 2020 19:37:30
DataPoint Un-verified.	Meghan York (b) (4) (b) (4)	27 Oct 2020 19:37:25
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	27 Oct 2020 19:37:25
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 05:52:56
DataPoint Verified.		16 Oct 2020 15:57:00
User entered 'allergies'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered '10'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:20:26
	(b) (4)	

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'UN UNK 1985'	Meghan York (b) (4)	04 Sep 2020 22:20:26
	(b) (4)	

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered '0'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 22:20:26

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 19:39:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 19:39:46
Data point term sent to Coder	System	27 Oct 2020 19:38:10
Coding entries removed.	Meghan York (b) (4)	27 Oct 2020 19:37:42
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 22:23:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 22:23:44
Data point term sent to Coder	System	04 Sep 2020 22:22:32
User entered 'Flonase'	Meghan York (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.		02 Nov 2020 09:55:23
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	Meghan York (b) (4)	27 Oct 2020 19:37:47
' answered with 'DONE' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Meghan York (b) (4)	27 Oct 2020 19:37:42
	(b) (4)	
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Meghan York (b) (4)	27 Oct 2020 19:37:42
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 05:53:39
DataPoint Verified.		16 Oct 2020 15:57:00
User entered 'allergies'	Meghan York (b) (4)	04 Sep 2020 22:21:36
	(b) (4)	

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered '50'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'Other (OTHER)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'mcg'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'Nasal (NASAL)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'UN UNK 2010'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered '0'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 22:21:36

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:24:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:24:45
Data point term sent to Coder	System	04 Sep 2020 22:23:37
User entered 'losartan'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'hypertension'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:47:35
DataPoint Un-verified.	Jill York (b) (4)	01 Feb 2021 20:49:34
User entered '75' reason for change: Data Entry Error	Jill York (b) (4)	01 Feb 2021 20:49:34
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered '25'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:22:41
	(b) (4)	

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'twice daily (BID)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'UN UNK 2017'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered '0'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 22:22:41

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE, PRODUCTSYNONYM: HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 22:24:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 22:24:45
Data point term sent to Coder	System	04 Sep 2020 22:23:37
User entered 'hctz'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'hypertension'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered '12.5'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'mg (mg)'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'once daily (QD)'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'Oral (ORAL)'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'UN UNK 2018'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
DataPoint Un-verified.	Meghan York (b) (4)	01 Dec 2020 19:51:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Dec 2020 19:51:41
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
DataPoint Un-verified.	Meghan York (b) (4)	01 Dec 2020 19:51:41
User entered '5 Nov 2020' reason for change: Data Entry Error	Meghan York (b) (4)	01 Dec 2020 19:51:41
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 15:57:00
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User entered '1'	System	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User entered '1'	System	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:59
User entered '804 (804)'	System	04 Sep 2020 22:23:29

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Jan 2021 17:20:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Jan 2021 17:20:50
Data point term sent to Coder	System	25 Jan 2021 17:19:35
User entered 'flu vaccine'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered 'Yes (Y)'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered 'flu prevention'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered 'unknown'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered 'Other (OTHER)'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered 'unknown'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered 'once (ONCE)'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered empty.	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered 'Oral (ORAL)'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered empty.	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered '25 Sep 2020'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered '0'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered 'No (N)'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered '25 Sep 2020'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:47:35
User entered 'No (N)'	Meghan York (b) (4)	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User entered empty.	System	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User entered empty.	System	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:25:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:54
User entered empty.	System	25 Jan 2021 17:19:20

US3142137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:25:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:58:09
DataPoint Un-verified.	Jill York (b) (4)	01 Apr 2021 22:15:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	01 Apr 2021 22:15:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:52:45
User entered 'No (N)'	Jami Wagner (b) (4)	18 Mar 2021 20:43:42
	(b) (4)	

US3142137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:25:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:58:22
User entered '04 Mar 2021'	Jill York (b) (4)	01 Apr 2021 22:15:43

US3142137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:25:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:58:22
User entered 'left radical kidney nephrectomy'	Jill York (b) (4)	01 Apr 2021 22:15:43

US3142137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:25:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:58:22
User entered 'Adverse Event (AE)'	Jill York (b) (4)	01 Apr 2021 22:15:43

US3142137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:25:34

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:58:22
User entered empty.	Jill York (b) (4)	01 Apr 2021 22:15:43

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:31:30
Reviewed for Safety.		02 Apr 2021 13:22:20
User entered 'USA-US064-2021-MRNA-1273-P301000009'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:31:32
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'Yes (Y)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:31:34
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'No (N)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:31:37
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'No (N)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:31:39
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'Yes (Y)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:04
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'No (N)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:07
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'No (N)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:09
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'No (N)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:17
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'Ripley'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:19
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'Hollister'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:21
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered '4190 East Woodmen Road Suite 210'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:23
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'Colorado Springs'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:26
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered '80920'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:30
User entered 'US'	System	02 Apr 2021 13:22:39

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 13:22:39

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:31:30
Reviewed for Safety.		02 Apr 2021 13:22:20
User entered 'USA-US064-2021-MRNA-1273-P301000009'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:31:32
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'Yes (Y)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:31:34
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'No (N)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:31:37
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'No (N)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:31:39
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'Yes (Y)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:04
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'No (N)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:07
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'No (N)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:09
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'No (N)'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:17
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'Ripley'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:19
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'Hollister'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:21
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered '4190 East Woodmen Road Suite 210'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:23
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered 'Colorado Springs'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:26
Reviewed for Safety.		02 Apr 2021 13:22:24
User entered '80920'	System	02 Apr 2021 13:20:59

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:32:30
User entered 'US'	System	02 Apr 2021 13:22:39

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:25:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 13:22:39

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:25:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:33:44
User entered '02/Apr/2021 09:22'	System	02 Apr 2021 13:22:39

US3142137

Folder: SAE USA-US064-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:25:34

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.	Ripley Hollister (b) (4)	18 Apr 2021 20:15:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:33:48
User entered 'I'		02 Apr 2021 13:22:39