

US3372137 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:13:43

All time stamps listed in this document are displayed in GMT

US3372137

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Participant ID

US3372137

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

US3372137

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
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) 16 Feb 2021 16:19:21

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Date of Informed Consent (<i>dd MMM yyyy</i>)	14 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) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 16:19:21

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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) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	ALLERGY - SULFA
Start date (dd MMM yyyy)	UN UNK 1962
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 1962
Start Year (derived)	1962
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372137

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	UMBILICAL HERNIA
Start date (dd MMM yyyy)	14 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	BILATERAL KNEE OSTEOARTHRITIS
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 (7)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN DEC 2010
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 DEC 2010
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2010
Start Year (derived)	2010
Stop Month and Year (derived)	DEC 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN DEC 2010
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 DEC 2010
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2010
Start Year (derived)	2010
Stop Month and Year (derived)	DEC 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	UTERINE POLYPS
Start date (dd MMM yyyy)	UN JAN 2019
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 JAN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	DILATION AND CURETTAGE
Start date (dd MMM yyyy)	UN JAN 2019
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 JAN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	RIGHT UPPER ARM BASAL CELL CARCINOMA
Start date (dd MMM yyyy)	UN UNK 1980
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 DEC 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	DEC 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	RIGHT UPPER ARM CURETTAGE AND ELECTRODESICCATION
Start date (dd MMM yyyy)	UN DEC 2018
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 DEC 2018
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	DEC 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	LEFT EAR CURETTAGE AND ELECTRODESICCATION
Start date (dd MMM yyyy)	UN APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 2019
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	APR 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	LEFT EAR BASAL CELL CARCINOMA
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	APR 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

Condition	LEFT LEG BASAL CELL CARCINOMA
Start date (dd MMM yyyy)	UN UNK 1980
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 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 06 Apr 2021 18:36:22

Generated On: 09 Jun 2021 17:13:43

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 14:40
Height (<i>xxx.x</i>)	177.8 cm
Weight (<i>xxx.x</i>)	83.1 kg
BMI (<i>xxx.x</i>)	26.28679 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) 16 Feb 2021 16:19:21

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 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) 16 Feb 2021 16:19:21

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Date of assessment (*dd MMM yyyy*) 14 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*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2002

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

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) 16 Feb 2021 16:19:21

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:19:22

Generated On: 09 Jun 2021 17:13:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 186398

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) 16 Feb 2021 16:20:45

Generated On: 09 Jun 2021 17:13:43

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) 16 Feb 2021 16:20:45

Generated On: 09 Jun 2021 17:13:43

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)	14 AUG 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 14:40
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 16:20:45

Generated On: 09 Jun 2021 17:13:43

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)	14 AUG 2020
Time of assessment (00:00-23:59)	16:55 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 16:55
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

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) 14 AUG 2020

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

Treatment Date and Time (derived) 14 AUG 2020 16:24

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) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 AUG 2020

Collection time (00:00-23:59)

15:28 (24 HR)

Collection date and time (derived)

14 AUG 2020 15:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:25	14 AUG 2020 15:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

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 17:13:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 17:13

PC Open Date & Time

14 AUG 2020 16:44

PC Close Date & Time

14 AUG 2020 19:14

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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 97.8 °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	15 AUG 2020 10:34
PC Open Date & Time	14 AUG 2020 20:09
PC Close Date & Time	15 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 09:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

97.0 °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

17 AUG 2020 09:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

18 AUG 2020 08:12

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 09:01

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

20 AUG 2020 08:16

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 09:06

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 17:14

PC Open Date & Time

14 AUG 2020 16:44

PC Close Date & Time

14 AUG 2020 19:14

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 10:35

PC Open Date & Time

14 AUG 2020 20:09

PC Close Date & Time

15 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 09:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 09:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	18 AUG 2020 08:12
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

19 AUG 2020 09:01

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 08:16

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 09:06

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 17:15
PC Open Date & Time	14 AUG 2020 16:44
PC Close Date & Time	14 AUG 2020 19:14

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 10:36
PC Open Date & Time	14 AUG 2020 20:09
PC Close Date & Time	15 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

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 ☒

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 09:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 09:01
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

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 ☒

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 08:12
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 09:02
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 08:17
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 09:07
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3372137

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 15:15
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	16:56 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 16:56
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3372137

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 15 SEP 2020

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

Treatment Date and Time (derived) 15 SEP 2020 16:16

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

US3372137

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 SEP 2020

Collection time (00:00-23:59)

15:38 (24 HR)

Collection date and time (derived)

15 SEP 2020 15:38

US3372137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

Collection date (dd MMM yyyy)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:37	15 SEP 2020 15:37
Nasopharyngeal Swab 2	No		

US3372137

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 17:03

PC Open Date & Time

15 SEP 2020 16:36

PC Close Date & Time

15 SEP 2020 19:06

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp	16 SEP 2020 06:51
PC Open Date & Time	15 SEP 2020 20:01
PC Close Date & Time	16 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 06:46

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

97.3 °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

18 SEP 2020 07:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 07:58

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 05:38

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 06:30

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

97.6 °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

22 SEP 2020 06:45

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 17:04

PC Open Date & Time

15 SEP 2020 16:36

PC Close Date & Time

15 SEP 2020 19:06

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 06:52

PC Open Date & Time

15 SEP 2020 20:01

PC Close Date & Time

16 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 06:46

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 07:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 07:58

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 05:38

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 06:31

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 06:46

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 17:05
PC Open Date & Time	15 SEP 2020 16:36
PC Close Date & Time	15 SEP 2020 19:06

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 06:52
PC Open Date & Time	15 SEP 2020 20:01
PC Close Date & Time	16 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

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 ☒

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 06:47
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

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 ☒

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 07:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

110 of 2702

EAB) (1725)

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 07:59
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

112 of 2702

EAB) (1725)

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 05:39
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

114 of 2702

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 06:31
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

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 ☒

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 06:46
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3372137

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

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) _____

US3372137

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

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.

US3372137

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

09:43 (24 HR)

Collection date and time (derived)

12 OCT 2020 09:43

US3372137

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:20:46

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 11:36:17

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

21 OCT 2020 10:51:16

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 06:41:40
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

11 NOV 2020 10:39:25

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 22:52:43

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 11:23:27

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

29 NOV 2020 03:04:20

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

06 DEC 2020 23:41:26

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☒

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 DEC 2020 09:26:10

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 DEC 2020 06:07:25
Patient Cloud Open Date & Time	20 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
138 of 2702	

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

28 DEC 2020 08:59:15

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 10:33:53
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

12 JAN 2021 12:22:09

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

20 JAN 2021 18:38:56

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	24 JAN 2021 22:37:07
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

31 JAN 2021 07:17:48

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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	09 FEB 2021 10:17:20
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 10:24:10

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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	23 FEB 2021 10:27:45
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

28 FEB 2021 06:19:16

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

09 MAR 2021 05:56:31

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

22 MAR 2021 17:07:22

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

30 MAR 2021 14:28:24

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

08 APR 2021 11:01:31

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

13 APR 2021 12:42:36

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 APR 2021 20:28:06
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

26 APR 2021 22:31:21

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

02 MAY 2021 08:53:54

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐
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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐
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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐
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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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="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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐
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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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°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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Patient Cloud Open Date & Time	14 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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°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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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°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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐
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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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="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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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="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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐ 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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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="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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐
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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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°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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
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Patient Cloud Close Date & Time	29 SEP 2022 23:59
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US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 <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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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"/>

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3372137

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:13:43

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
Yes	No	28 FEB 2021 06:19:36

US3372137

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 17 Mar 2021 17:50:19

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 17 Mar 2021 17:50:19

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 13:17:28

Generated On: 09 Jun 2021 17:13:43

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) _____

US3372137

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

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.

US3372137

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

15:02 (24 HR)

Collection date and time (derived)

23 MAR 2021 15:02

US3372137

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 15:54:02

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 15:54:02

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Date of Contact	21 DEC 2020
Time of Contact	14:00
Date and Time of Contact (derived)	21 DEC 2020 14:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input checked="" type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Symptom Day

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

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Symptom Day

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

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Symptom Day

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

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Feb 2021 16:19:20

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Symptom Day

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

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

361 of 2702

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Date of Visit	21 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	21 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 22 Apr 2021 20:21:35

Generated On: 09 Jun 2021 17:13:43

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	23 DEC 2020
Day 5	Yes	25 DEC 2020
Day 7	Yes	27 DEC 2020
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3372137

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	14:05 (24 HR)
Vital Signs Date and Time (derived)	21 DEC 2020 14:05
Height (<i>xxx.x</i>)	70 in
Weight (<i>xxx.x</i>)	176.3 lb
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED FOREHEAD
Pulse (<i>xxx</i>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372137

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 DEC 2020

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

US3372137

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 DEC 2020

US3372137

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 21:51:09

Generated On: 09 Jun 2021 17:13:43

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

Visit date (dd MMM yyyy)	26 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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US3372137

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

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 16:33:15

Generated On: 09 Jun 2021 17:13:43

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

US3372137

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 21:51:09

Generated On: 09 Jun 2021 17:13:43

Height	177.8 cm
Weight	83.1 kg
BMI (xxx.x)	26.28679

US3372137

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 21:51:09

Generated On: 09 Jun 2021 17:13:43

Height	177.8 cm
Weight	83.1 kg
BMI (xxx.x)	26.28679
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 13:30
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED FOREHEAD
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3372137

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 21:51:09

Generated On: 09 Jun 2021 17:13:43

Height	177.8 cm
Weight	83.1 kg
BMI (xxx.x)	26.28679
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	15:27 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 15:27
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED FOREHEAD
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3372137

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 21:51:09

Generated On: 09 Jun 2021 17:13:43

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.

US3372137

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 21:51:09

Generated On: 09 Jun 2021 17:13:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

What was the treatment time? (00:00-23:59) 14:56 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 14:56

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

US3372137

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 21:51:09

Generated On: 09 Jun 2021 17:13:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

13:07 (24 HR)

Collection date and time (derived)

26 JAN 2021 13:07

US3372137

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 21:51:09

Generated On: 09 Jun 2021 17:13:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00 - 23:59)

13:05

Collection Date and Time (derived)

26 JAN 2021 13:05

US3372137

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:19:21

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 23:12:17

Generated On: 09 Jun 2021 17:13:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 23:12:17

Generated On: 09 Jun 2021 17:13:43

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	09:19 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 09:19
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 23:12:17

Generated On: 09 Jun 2021 17:13:43

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)	24 FEB 2021
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 11:08
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3372137

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 23:12:17

Generated On: 09 Jun 2021 17:13:43

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.

US3372137

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 23:12:17

Generated On: 09 Jun 2021 17:13:43

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) 24 FEB 2021

What was the treatment time? (00:00-23:59) 10:33 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 10:33

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

What was the frequency of the study treatment dosing? ONCE

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

US3372137

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 23:12:17

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 16:33:15

Generated On: 09 Jun 2021 17:13:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372137

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 16:33:15

Generated On: 09 Jun 2021 17:13:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372137

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:50 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 14:50
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372137

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

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.

US3372137

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	15:02 (24 HR)
Collection date and time (derived)	23 MAR 2021 15:02

US3372137

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

AEID	USA-US056-2021-MRNA-1273-P30 1000004
Adverse event	DIZZINESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 JAN 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)	22 JAN 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)	19 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	22 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

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

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Folder: Adverse Events

Form: Adverse Events (1)

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SUBJECT US 3372137
PRESENTED AN EPISODE OF
DIZZINESS FOR WHICH SHE
WAS HOSPITALIZED ON 19
JANUARY 2021. THE SUBJECT
WAS DISCHARGED ON 22 JAN
2021. SUBJECT WAS
PRESCRIBED MECLIZINE PRN,
BUT SHE CONFIRMED SHE DID
NOT TAKE THE MEDICATION.
AT THE MOMENT OF THE SITE'S
VISIT THE SUBJECT DID NOT
PRESENT ANY SYMPTOMS AND
SHE STATED FEELING GOOD.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 18:53:11

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AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Form: Adverse Events (2)

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 07 Apr 2021 18:53:11

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AEID

Adverse event

SINUS CONGESTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input 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)	12 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

AEID	
Adverse event	WHEEZING
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 07 Apr 2021 18:53:11

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

AEID

Adverse event

UPPER RESPIRATORY
INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 07 Apr 2021 18:53:11

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 16:19:20

Generated On: 09 Jun 2021 17:13:43

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

	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 2008	
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) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

	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 2008	
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) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication DIETARY SUPPLEMENT

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

	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 checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Name of Medication CALCIUM/MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

	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 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) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Name of Medication AMOXICLAV

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION

Dose per administration 875/125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication SINUS CONGESTION

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

	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)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

Name of Medication TESSALON CAPSULE

Prophylaxis Yes ☐
No ☒

Indication COUGH

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Mar 2021 21:32:33

Generated On: 09 Jun 2021 17:13:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Mar 2021 15:30:33

Generated On: 09 Jun 2021 17:13:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Mar 2021 15:30:33

Generated On: 09 Jun 2021 17:13:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 JAN 2021	MRI CERVICAL SPINE	Adverse Event	
21 JAN 2021	MRI BRAIN	Adverse Event	
19 JAN 2021	CAT HEAD/BRAIN W/O CONTRAST	Adverse Event	
19 JAN 2021	CHEST X-RAY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:13:43

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

US3372137

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:13:43

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 ☐

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

SAEID	USA-US056-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

SAEID	USA-US056-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	27/JAN/2021 18:49
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

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

SAEID	USA-US056-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/FEB/2021 01:24
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

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

SAEID	USA-US056-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/MAR/2021 10:30
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

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 07 Apr 2021 18:53:11

Generated On: 09 Jun 2021 17:13:43

SAEID	USA-US056-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	07/APR/2021 10:38
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

US3372137 (Prod: Palm Beach Research Center)

US3372137

Form: Participant Creation

Generated On: 09 Jun 2021 17:13:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'US3372137'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:39:47

US3372137

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:46:47

US3372137

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:39:48

US3372137

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[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 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:46:47

US3372137

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'SCRN'	System	14 Aug 2020 19:46:47

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:39:49

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '73'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'YEARS'	System	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '73'	System	14 Aug 2020 19:50:02

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Female (F)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'I'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:13:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:47:16

US3372137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:50:02

US3372137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Aug 2020'	System	14 Aug 2020 19:50:02

US3372137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2020'	System	14 Aug 2020 19:50:02

US3372137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Amendment 2 (2)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:50:02

US3372137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:50:02

US3372137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:43

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:50:02

US3372137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:50:02

US3372137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:50:02

US3372137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 18:39:48

US3372137

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:13:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'I'	System	14 Aug 2020 19:50:09

US3372137

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:50:09

US3372137

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:13:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:07:19

US3372137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:33:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:33:51
Data point term sent to Coder	System	01 Oct 2020 18:32:55
User entered 'allergy - sulfa'	Peter Jacob (b) (4)	01 Oct 2020 18:32:14

US3372137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 1962'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:14

US3372137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:14

US3372137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:14

US3372137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:14

US3372137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:14

US3372137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 1962'	System	01 Oct 2020 18:32:14

US3372137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '1962'	System	01 Oct 2020 18:32:14

US3372137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:32:14

US3372137

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:32:14

US3372137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:33:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:33:51
Data point term sent to Coder	System	01 Oct 2020 18:32:56
User entered 'postmenopausal'	Peter Jacob (b) (4)	01 Oct 2020 18:32:26

US3372137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 2002'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:32:26

US3372137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:26

US3372137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:26

US3372137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:32:26

US3372137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:26

US3372137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2002'	System	01 Oct 2020 18:32:26

US3372137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2002'	System	01 Oct 2020 18:32:26

US3372137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:32:26

US3372137

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:32:26

US3372137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:33:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:33:50
Data point term sent to Coder	System	01 Oct 2020 18:32:56
User entered 'depression'	Peter Jacob (b) (4)	01 Oct 2020 18:32:41

US3372137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 2008'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:41

US3372137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:41

US3372137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:32:41

US3372137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:41

US3372137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:41

US3372137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2008'	System	01 Oct 2020 18:32:41

US3372137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2008'	System	01 Oct 2020 18:32:41

US3372137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:32:41

US3372137

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:32:41

US3372137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:34:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:34:00
Data point term sent to Coder	System	01 Oct 2020 18:32:56
User entered 'anxiety'	Peter Jacob (b) (4)	01 Oct 2020 18:32:50

US3372137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 2008'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:50

US3372137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:50

US3372137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:50

US3372137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:50

US3372137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:32:50

US3372137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2008'	System	01 Oct 2020 18:32:50

US3372137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2008'	System	01 Oct 2020 18:32:50

US3372137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:32:50

US3372137

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:32:50

US3372137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:35:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:35:30
Data point term sent to Coder	System	01 Oct 2020 18:33:57
User entered 'umbilical hernia'	Peter Jacob (b) (4)	01 Oct 2020 18:33:01

US3372137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User closed query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:01:52
Query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you' answered with 'patient came into visit with condition but was not diagnosed until after visit when they saw their PCP' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Nov 2020 23:07:23
User opened query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:19:35
User entered '14 Aug 2020'	Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:01

US3372137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:01

US3372137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:01

US3372137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:33:01

US3372137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:01

US3372137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Aug 2020'	System	01 Oct 2020 18:33:01

US3372137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2020'	System	01 Oct 2020 18:33:01

US3372137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:33:01

US3372137

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:33:01

US3372137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
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)	01 Oct 2020 18:34:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:34:55
Data point term sent to Coder	System	01 Oct 2020 18:33:57
User entered 'bilateral knee osteoarthritis'	Peter Jacob (b) (4)	01 Oct 2020 18:33:24

US3372137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 2000'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:24

US3372137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:24

US3372137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:24

US3372137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:33:24

US3372137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:24

US3372137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2000'	System	01 Oct 2020 18:33:24

US3372137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2000'	System	01 Oct 2020 18:33:24

US3372137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:33:24

US3372137

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:33:24

US3372137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:34:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:34:55
Data point term sent to Coder	System	01 Oct 2020 18:33:57
User entered 'appendicitis'	Peter Jacob (b) (4)	01 Oct 2020 18:33:35

US3372137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Dec 2010'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:35

US3372137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:35

US3372137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:33:35

US3372137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Dec 2010'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:35

US3372137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:35

US3372137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Dec 2010'	System	01 Oct 2020 18:33:35

US3372137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2010'	System	01 Oct 2020 18:33:35

US3372137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Dec 2010'	System	01 Oct 2020 18:33:35

US3372137

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2010'	System	01 Oct 2020 18:33:35

US3372137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:34:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:34:55
Data point term sent to Coder	System	01 Oct 2020 18:33:57
User entered 'appendectomy'	Peter Jacob (b) (4)	01 Oct 2020 18:33:49

US3372137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Dec 2010'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:33:49

US3372137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:49

US3372137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:49

US3372137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Dec 2010'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:49

US3372137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:33:49

US3372137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Dec 2010'	System	01 Oct 2020 18:33:49

US3372137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2010'	System	01 Oct 2020 18:33:49

US3372137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Dec 2010'	System	01 Oct 2020 18:33:49

US3372137

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2010'	System	01 Oct 2020 18:33:49

US3372137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine neoplasms, PT: Uterine polyp, LLT: Uterine polyp - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:35:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:35:49
Data point term sent to Coder	System	01 Oct 2020 18:34:59
User entered 'uterine polyps'	Peter Jacob (b) (4)	01 Oct 2020 18:34:04

US3372137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Jan 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:04

US3372137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:04

US3372137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:34:04

US3372137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Jan 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:04

US3372137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:04

US3372137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2019'	System	01 Oct 2020 18:34:04

US3372137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2019'	System	01 Oct 2020 18:34:04

US3372137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2019'	System	01 Oct 2020 18:34:04

US3372137

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2019'	System	01 Oct 2020 18:34:04

US3372137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Uterine dilation and curettage, LLT: Uterine dilation and curettage - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:35:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:35:50
Data point term sent to Coder	System	01 Oct 2020 18:34:58
User entered 'dilation and curettage'	Peter Jacob (b) (4)	01 Oct 2020 18:34:22

US3372137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Jan 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:22

US3372137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:22

US3372137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:22

US3372137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Jan 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:22

US3372137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:22

US3372137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2019'	System	01 Oct 2020 18:34:22

US3372137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2019'	System	01 Oct 2020 18:34:22

US3372137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2019'	System	01 Oct 2020 18:34:22

US3372137

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2019'	System	01 Oct 2020 18:34:22

US3372137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 09:08:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 09:08:40
Data point term sent to Coder	System	01 Oct 2020 18:34:59
User entered 'right upper arm basal cell carcinoma'	Peter Jacob (b) (4)	01 Oct 2020 18:34:45

US3372137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 1980'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:45

US3372137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:45

US3372137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:45

US3372137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Dec 2018'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:34:45

US3372137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:34:45

US3372137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 1980'	System	01 Oct 2020 18:34:45

US3372137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '1980'	System	01 Oct 2020 18:34:45

US3372137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Dec 2018'	System	01 Oct 2020 18:34:45

US3372137

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2018'	System	01 Oct 2020 18:34:45

US3372137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Electrodesiccation, LLT: Electrodesiccation and curettage - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 09:08:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 09:08:40
Data point term sent to Coder	System	01 Oct 2020 18:36:00
User entered 'right upper arm curettage and electrodesiccation'	Peter Jacob (b) (4)	01 Oct 2020 18:35:15

US3372137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Dec 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:35:15

US3372137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:35:15

US3372137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:35:15

US3372137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Dec 2018'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:35:15

US3372137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:35:15

US3372137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Dec 2018'	System	01 Oct 2020 18:35:15

US3372137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2018'	System	01 Oct 2020 18:35:15

US3372137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Dec 2018'	System	01 Oct 2020 18:35:15

US3372137

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2018'	System	01 Oct 2020 18:35:15

US3372137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Electrodesiccation, LLT: Electrodesiccation and curettage - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 12:19:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 12:19:45
Data point term sent to Coder	System	01 Oct 2020 18:36:03
User entered 'left ear curettage and electrodesiccation'	Peter Jacob (b) (4)	01 Oct 2020 18:35:43

US3372137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Apr 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:35:43

US3372137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:35:43

US3372137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:35:43

US3372137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Apr 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:35:43

US3372137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:35:43

US3372137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Apr 2019'	System	01 Oct 2020 18:35:43

US3372137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2019'	System	01 Oct 2020 18:35:43

US3372137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Apr 2019'	System	01 Oct 2020 18:35:43

US3372137

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2019'	System	01 Oct 2020 18:35:43

US3372137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Electrodesiccation, LLT: Electrodesiccation and curettage - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 22:00:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 22:00:24
Data point term sent to Coder	System	01 Oct 2020 18:37:04
User entered 'left leg curettage and electrodesiccation'	Peter Jacob (b) (4)	01 Oct 2020 18:36:17

US3372137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Jan 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:17

US3372137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:17

US3372137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:17

US3372137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Jan 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:17

US3372137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:17

US3372137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2020'	System	01 Oct 2020 18:36:17

US3372137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2020'	System	01 Oct 2020 18:36:17

US3372137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2020'	System	01 Oct 2020 18:36:17

US3372137

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2020'	System	01 Oct 2020 18:36:17

US3372137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	04 Oct 2020 17:17:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Oct 2020 17:17:46
Data point term sent to Coder	System	01 Oct 2020 18:37:04
User entered 'left ear basal cell carcinoma'	Peter Jacob (b) (4)	01 Oct 2020 18:36:38

US3372137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 1980'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:38

US3372137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:38

US3372137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:38

US3372137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Apr 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:38

US3372137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:38

US3372137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 1980'	System	01 Oct 2020 18:36:38

US3372137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '1980'	System	01 Oct 2020 18:36:38

US3372137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Apr 2019'	System	01 Oct 2020 18:36:38

US3372137

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2019'	System	01 Oct 2020 18:36:38

US3372137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	04 Oct 2020 17:17:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Oct 2020 17:17:46
Data point term sent to Coder	System	01 Oct 2020 18:37:06
User entered 'left leg basal cell carcinoma'	Peter Jacob (b) (4)	01 Oct 2020 18:36:58

US3372137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 1980'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:58

US3372137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:58

US3372137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:36:58

US3372137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Jan 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:58

US3372137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:36:58

US3372137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 1980'	System	01 Oct 2020 18:36:58

US3372137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '1980'	System	01 Oct 2020 18:36:58

US3372137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2020'	System	01 Oct 2020 18:36:58

US3372137

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2020'	System	01 Oct 2020 18:36:58

US3372137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:38:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:38:56
Data point term sent to Coder	System	01 Oct 2020 18:38:06
User entered 'edema bilateral lower extremities'	Peter Jacob (b) (4)	01 Oct 2020 18:37:09

US3372137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 2010'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:37:09

US3372137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:37:09

US3372137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:37:09

US3372137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:37:09

US3372137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:37:09

US3372137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2010'	System	01 Oct 2020 18:37:09

US3372137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2010'	System	01 Oct 2020 18:37:09

US3372137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:37:09

US3372137

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	01 Oct 2020 18:37:09

US3372137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:24:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:24:22
User signature succeeded.	Mira Baron (b) (4) (b) (4)	06 Apr 2021 18:36:22
Data point term sent to Coder	System	06 Apr 2021 17:57:10
User entered 'Juvederm (Cosmetic)'	(b) (4), (b) (6)	06 Apr 2021 17:56:39

US3372137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 18:36:22
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:56:39

US3372137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 18:36:22
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:56:39

US3372137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 18:36:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:56:39

US3372137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 18:36:22
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:56:39

US3372137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 18:36:22
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:56:39

US3372137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2016'	System	06 Apr 2021 17:56:39

US3372137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2016'	System	06 Apr 2021 17:56:39

US3372137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'Jan 2016'	System	06 Apr 2021 17:56:39

US3372137

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '2016'	System	06 Apr 2021 17:56:39

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:57:54

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:57:54

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14:40'	Peter Jacob (b) (4)	19 Aug 2020 23:57:54

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '14 Aug 2020 14:40'	System	19 Aug 2020 23:57:54

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User closed query 'Per CDM: Please review and confirm data. Thank you' (Site from DM).	(b) (4)	
Query 'Per CDM: Please review and confirm data. Thank you' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 18:42:45
Query 'Per CDM: Please review and confirm data. Thank you' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4)	25 Sep 2020 17:33:24
User closed query 'Height reported is out of range <= System 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	(b) (4)	25 Sep 2020 17:33:14
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	25 Sep 2020 17:33:14
User entered '177.8' cm reason for change: Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 17:33:14
Amendment Manager: User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	(b) (4)	
User opened query 'Per CDM: Please review and confirm data. Thank you' (Site from DM).	System	16 Sep 2020 23:57:48
User entered '36.6' cm	Peter Jacob (b) (4)	15 Sep 2020 15:29:27
DataPoint set to visible.	(b) (4)	19 Aug 2020 23:57:54
	System	14 Aug 2020 19:50:09

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '83.1' kg	(b) (4) Peter Jacob (b) (4)	19 Aug 2020 23:57:54
DataPoint set to visible.	(b) (4) System	14 Aug 2020 19:50:09

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '26.28679'	System	25 Sep 2020 17:33:14
Amendment Manager: User entered '620.35295'	System	16 Sep 2020 23:57:48
User entered '620.4'	System	19 Aug 2020 23:57:54
DataPoint set to visible.	System	14 Aug 2020 19:50:09

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'kg/m2'	System	19 Aug 2020 23:57:54
DataPoint set to visible.	System	14 Aug 2020 19:50:09

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:33:38
User entered '36.6' C	Peter Jacob (b) (4)	19 Aug 2020 23:57:54
	(b) (4)	

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:33:38
User entered 'Oral (Oral)'	Peter Jacob (b) (4)	19 Aug 2020 23:57:54
	(b) (4)	

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:57:54

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:33:38
User entered '70'	Peter Jacob (b) (4)	19 Aug 2020 23:57:54
	(b) (4)	

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'bpm'	System	19 Aug 2020 23:57:54

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:33:38
User entered '18'	Peter Jacob (b) (4)	19 Aug 2020 23:57:54
	(b) (4)	

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'breaths/min'	System	19 Aug 2020 23:57:54

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:33:38
User entered '126'	Peter Jacob (b) (4)	19 Aug 2020 23:57:54
	(b) (4)	

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'mmHg'	System	19 Aug 2020 23:57:54

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:33:38
User entered '80'	Peter Jacob (b) (4)	19 Aug 2020 23:57:54
	(b) (4)	

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'mmHg'	System	19 Aug 2020 23:57:54

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 12:31:41

US3372137

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41

US3372137

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:57:59

US3372137

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	30 Sep 2020 21:34:48
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		15 Sep 2020 20:34:10
User entered '14 Aug 2020'	Peter Jacob (b) (4)	19 Aug 2020 23:57:59
	(b) (4)	

US3372137

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:19

US3372137

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:13:43

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	19 Aug 2020 23:58:19

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:13:43

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 11:30:36
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:37:36
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 09:40:15
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:19

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:13:43

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:19

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:13:43

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:19

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:13:43

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4)	19 Aug 2020 23:58:19

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 2002'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:19

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:13:43

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

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Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'I'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

US3372137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

US3372137

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:13:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:05

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:20

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:20

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:20

US3372137

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'VISIT1'	System	14 Aug 2020 19:51:20

US3372137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 19:34:21

US3372137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:43

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:39:03
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:39:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 19:34:21
User entered '186398' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 19:34:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:43

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 19:34:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:43

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)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:54

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:43

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)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:54

US3372137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:43

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:54

US3372137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:43

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:54

US3372137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 19:51:54

US3372137

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:13:43

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:39:55
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:21:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:22:33

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:20:27
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:02:19
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:01:45
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:51:43
User entered '177.8' cm	Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:01:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:01:45
User entered '83.1' kg	Peter Jacob (b) (4)	19 Aug 2020 23:58:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:20:27
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:02:19
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:01:45
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:51:43
User entered '177.8' cm	Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:01:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:01:45
User entered '83.1' kg	Peter Jacob (b) (4)	19 Aug 2020 23:58:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	19 Aug 2020 23:58:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '14 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '14:40'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '14 Aug 2020 14:40'	System	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '70'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'bpm'	System	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '18'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'breaths/min'	System	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '126'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'mmHg'	System	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '80'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'mmHg'	System	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:20:27
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:02:19
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:01:45
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:51:43
User entered '177.8' cm	Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:01:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:01:45
User entered '83.1' kg	Peter Jacob (b) (4)	19 Aug 2020 23:58:52

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '14 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 10:00:53
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post-dose vital signs must be collected at least 30 minutes after dose time' (Site from System).	Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:19
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).		19 Aug 2020 23:59:13
User entered '16:55'	Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '14 Aug 2020 16:55'	System	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '36.4' C	(b) (4) Peter Jacob (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '66'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'bpm'	System	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '18'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'breaths/min'	System	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '140'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'mmHg'	System	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '72'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'mmHg'	System	19 Aug 2020 23:59:13

US3372137

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:25

US3372137

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	19 Aug 2020 23:59:25

US3372137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:31:21

US3372137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:31:21

US3372137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

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 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:31:21

US3372137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 20:31:21

US3372137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:31:21

US3372137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '16:24'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:31:21

US3372137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '14 Aug 2020 16:24'	System	14 Aug 2020 20:31:21

US3372137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:31:21

US3372137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'ONCE'	System	14 Aug 2020 20:31:21

US3372137

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 20:31:21

US3372137

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:31:48

US3372137

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:31:48

US3372137

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '15:28'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:31:48

US3372137

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '14 Aug 2020 15:28'	System	14 Aug 2020 20:31:48

US3372137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:13:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:32:09

US3372137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:32:09

US3372137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:32:09

US3372137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '15:25'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:32:09

US3372137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '14 Aug 2020 15:25'	System	14 Aug 2020 20:32:09

US3372137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:32:09

US3372137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:32:09

US3372137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	14 Aug 2020 20:32:09

US3372137

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered empty.	System	14 Aug 2020 20:32:09

US3372137

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	19 Aug 2020 23:59:35

US3372137

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'I'	System	19 Aug 2020 23:59:35

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:13:28', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '10addb11-3ba3-4981-b052-aeb5f84e5127' User entered 'Yes (Y)'	System	14 Aug 2020 21:14:03
	System	14 Aug 2020 21:14:03

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:13:44', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '10addb11-3ba3-4981-b052-aeb5f84e5127' User entered '97.6'	System	14 Aug 2020 21:14:03
	System	14 Aug 2020 21:14:03

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:13:50', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '10addb11-3ba3-4981-b052-aeb5f84e5127'	System	14 Aug 2020 21:14:03
User entered 'No (N)'	System	14 Aug 2020 21:14:03

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:13:56', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '10addb11-3ba3-4981-b052-aeb5f84e5127'	System	14 Aug 2020 21:14:03
User entered '14 Aug 2020 17:13'	System	14 Aug 2020 21:14:03

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '14 Aug 2020 16:44'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '14 Aug 2020 19:14'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:34:19', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b8d60d91-ec30-4f39-bfb2-b804607da587' User entered 'Yes (Y)'	System	15 Aug 2020 14:34:46
	System	15 Aug 2020 14:34:46

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:34:27', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b8d60d91-ec30-4f39-bfb2-b804607da587' User entered '97.8'	System	15 Aug 2020 14:34:46
	System	15 Aug 2020 14:34:46

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:34:32', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b8d60d91-ec30-4f39-bfb2-b804607da587'	System	15 Aug 2020 14:34:46
User entered 'No (N)'	System	15 Aug 2020 14:34:46

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:34:42', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b8d60d91-ec30-4f39-bfb2-b804607da587'	System	15 Aug 2020 14:34:46
User entered '15 Aug 2020 10:34'	System	15 Aug 2020 14:34:46

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '14 Aug 2020 20:09'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 2'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:00:06', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'aeb3747c-9956-4d70-a603-552e85198bd6' User entered 'Yes (Y)'	System	16 Aug 2020 13:00:31
	System	16 Aug 2020 13:00:31

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:00:13', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'aeb3747c-9956-4d70-a603-552e85198bd6' User entered '96.7'	System	16 Aug 2020 13:00:31
	System	16 Aug 2020 13:00:31

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:00:19', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'aeb3747c-9956-4d70-a603-552e85198bd6'	System	16 Aug 2020 13:00:31
User entered 'No (N)'	System	16 Aug 2020 13:00:31

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:00:29', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'aeb3747c-9956-4d70-a603-552e85198bd6'	System	16 Aug 2020 13:00:31
User entered '16 Aug 2020 09:00'	System	16 Aug 2020 13:00:31

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 3'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:00:06', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '529ddffb-9544-4fd4-808a-bf65f308b8c6' User entered 'Yes (Y)'	System	17 Aug 2020 13:00:22
	System	17 Aug 2020 13:00:22

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:00:12', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '529ddffb-9544-4fd4-808a-bf65f308b8c6' User entered '97.0'	System	17 Aug 2020 13:00:22
	System	17 Aug 2020 13:00:22

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:00:15', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '529ddffb-9544-4fd4-808a-bf65f308b8c6'	System	17 Aug 2020 13:00:22
User entered 'No (N)'	System	17 Aug 2020 13:00:22

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:00:20', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '529ddffb-9544-4fd4-808a-bf65f308b8c6'	System	17 Aug 2020 13:00:22
User entered '17 Aug 2020 09:00'	System	17 Aug 2020 13:00:22

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 4'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:11:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '177590b7-fcf2-4d2f-a46e-79d322d771c2'	System	18 Aug 2020 12:12:03
User entered 'Yes (Y)'	System	18 Aug 2020 12:12:03

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:11:52', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '177590b7-fcf2-4d2f-a46e-79d322d771c2' User entered '96.6'	System	18 Aug 2020 12:12:03
	System	18 Aug 2020 12:12:03

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:11:55', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '177590b7-fcf2-4d2f-a46e-79d322d771c2'	System	18 Aug 2020 12:12:03
User entered 'No (N)'	System	18 Aug 2020 12:12:03

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '177590b7-fcf2-4d2f-a46e-79d322d771c2'	System	18 Aug 2020 12:12:03
User entered '18 Aug 2020 08:12'	System	18 Aug 2020 12:12:03

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 5'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:01:26', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '8c4679b7-a8be-479a-98e3-e0cf2cad164a' User entered 'Yes (Y)'	System	19 Aug 2020 13:01:41
	System	19 Aug 2020 13:01:41

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:01:31', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '8c4679b7-a8be-479a-98e3-e0cf2cad164a' User entered '97.4'	System	19 Aug 2020 13:01:41
	System	19 Aug 2020 13:01:41

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:01:35', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '8c4679b7-a8be-479a-98e3-e0cf2cad164a' User entered 'No (N)'	System	19 Aug 2020 13:01:41
	System	19 Aug 2020 13:01:41

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:01:39', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '8c4679b7-a8be-479a-98e3-e0cf2cad164a'	System	19 Aug 2020 13:01:41
User entered '19 Aug 2020 09:01'	System	19 Aug 2020 13:01:41

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 6'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:11', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f1e0abbf-0e6c-44d5-aed4-04661f6aa4e8'	System	20 Aug 2020 12:16:27
User entered 'Yes (Y)'	System	20 Aug 2020 12:16:27

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:16', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f1e0abbf-0e6c-44d5-aed4-04661f6aa4e8' User entered '97.1'	System	20 Aug 2020 12:16:27
	System	20 Aug 2020 12:16:27

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:20', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f1e0abbf-0e6c-44d5-aed4-04661f6aa4e8'	System	20 Aug 2020 12:16:27
User entered 'No (N)'	System	20 Aug 2020 12:16:27

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:25', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f1e0abbf-0e6c-44d5-aed4-04661f6aa4e8'	System	20 Aug 2020 12:16:27
User entered '20 Aug 2020 08:16'	System	20 Aug 2020 12:16:27

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 7'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:06:19', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '536ab82f-0d9e-4158-ad72-a5e76b9f2027'	System	21 Aug 2020 13:06:41
User entered 'Yes (Y)'	System	21 Aug 2020 13:06:41

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:06:25', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '536ab82f-0d9e-4158-ad72-a5e76b9f2027' User entered '97.3'	System	21 Aug 2020 13:06:41
	System	21 Aug 2020 13:06:41

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:06:34', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '536ab82f-0d9e-4158-ad72-a5e76b9f2027'	System	21 Aug 2020 13:06:41
User entered 'No (N)'	System	21 Aug 2020 13:06:41

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:06:39', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '536ab82f-0d9e-4158-ad72-a5e76b9f2027'	System	21 Aug 2020 13:06:41
User entered '21 Aug 2020 09:06'	System	21 Aug 2020 13:06:41

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:14:09', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '39ac84ff-991f-4412-8056-01b36d8b9505'	System	14 Aug 2020 21:14:40
User entered 'None (1)'	System	14 Aug 2020 21:14:40

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:14:17', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '39ac84ff-991f-4412-8056-01b36d8b9505'	System	14 Aug 2020 21:14:40
User entered 'No (N)'	System	14 Aug 2020 21:14:40

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:14:22', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '39ac84ff-991f-4412-8056-01b36d8b9505'	System	14 Aug 2020 21:14:40
User entered 'No (N)'	System	14 Aug 2020 21:14:40

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:14:27', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '39ac84ff-991f-4412-8056-01b36d8b9505'	System	14 Aug 2020 21:14:40
User entered 'None (1)'	System	14 Aug 2020 21:14:40

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:14:36', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '39ac84ff-991f-4412-8056-01b36d8b9505'	System	14 Aug 2020 21:14:40
User entered '14 Aug 2020 17:14'	System	14 Aug 2020 21:14:40

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '14 Aug 2020 16:44'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '14 Aug 2020 19:14'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:34:52', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b181867c-0277-4d11-8d47-ccc1e1d11fb3'	System	15 Aug 2020 14:35:36
User entered 'None (1)'	System	15 Aug 2020 14:35:36

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:35:02', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b181867c-0277-4d11-8d47-ccc1e1d11fb3'	System	15 Aug 2020 14:35:36
User entered 'No (N)'	System	15 Aug 2020 14:35:36

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:35:09', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b181867c-0277-4d11-8d47-ccc1e1d11fb3' User entered 'No (N)'	System	15 Aug 2020 14:35:36
	System	15 Aug 2020 14:35:36

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:35:24', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b181867c-0277-4d11-8d47-ccc1e1d11fb3'	System	15 Aug 2020 14:35:36
User entered 'None (1)'	System	15 Aug 2020 14:35:36

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:35:31', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b181867c-0277-4d11-8d47-ccc1e1d11fb3'	System	15 Aug 2020 14:35:36
User entered '15 Aug 2020 10:35'	System	15 Aug 2020 14:35:36

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '14 Aug 2020 20:09'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 2'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:00:46', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b4c3dcd7-697a-4137-bc80-8ffcf31e708d'	System	16 Aug 2020 13:01:19
User entered 'None (1)'	System	16 Aug 2020 13:01:19

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:00:49', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b4c3dcd7-697a-4137-bc80-8ffcf31e708d' User entered 'No (N)'	System	16 Aug 2020 13:01:19
	System	16 Aug 2020 13:01:19

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:00:53', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b4c3dcd7-697a-4137-bc80-8ffcf31e708d' User entered 'No (N)'	System	16 Aug 2020 13:01:19
	System	16 Aug 2020 13:01:19

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:01:10', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b4c3dcd7-697a-4137-bc80-8ffcf31e708d'	System	16 Aug 2020 13:01:19
User entered 'None (1)'	System	16 Aug 2020 13:01:19

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:01:17', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b4c3dcd7-697a-4137-bc80-8ffcf31e708d' User entered '16 Aug 2020 09:01'	System	16 Aug 2020 13:01:19
	System	16 Aug 2020 13:01:19

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 3'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:00:24', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a173f0c5-6be7-45f8-82d7-ccaefc40c9fb'	System	17 Aug 2020 13:00:54
User entered 'None (1)'	System	17 Aug 2020 13:00:54

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:00:27', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a173f0c5-6be7-45f8-82d7-ccaefc40c9fb'	System	17 Aug 2020 13:00:54
User entered 'No (N)'	System	17 Aug 2020 13:00:54

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:00:30', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a173f0c5-6be7-45f8-82d7-ccaefc40c9fb'	System	17 Aug 2020 13:00:54
User entered 'No (N)'	System	17 Aug 2020 13:00:54

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:00:46', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a173f0c5-6be7-45f8-82d7-ccaefc40c9fb'	System	17 Aug 2020 13:00:54
User entered 'None (1)'	System	17 Aug 2020 13:00:54

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:00:52', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a173f0c5-6be7-45f8-82d7-ccaefc40c9fb'	System	17 Aug 2020 13:00:54
User entered '17 Aug 2020 09:00'	System	17 Aug 2020 13:00:54

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 4'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:05', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'caeb7e18-98b8-4218-8aa2-c16046b6ff46'	System	18 Aug 2020 12:12:26
User entered 'None (1)'	System	18 Aug 2020 12:12:26

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:09', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'caeb7e18-98b8-4218-8aa2-c16046b6ff46'	System	18 Aug 2020 12:12:26
User entered 'No (N)'	System	18 Aug 2020 12:12:26

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:14', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'caeb7e18-98b8-4218-8aa2-c16046b6ff46'	System	18 Aug 2020 12:12:26
User entered 'No (N)'	System	18 Aug 2020 12:12:26

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:18', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'caeb7e18-98b8-4218-8aa2-c16046b6ff46' User entered 'None (1)'	System	18 Aug 2020 12:12:26
	System	18 Aug 2020 12:12:26

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:23', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'caeb7e18-98b8-4218-8aa2-c16046b6ff46'	System	18 Aug 2020 12:12:26
User entered '18 Aug 2020 08:12'	System	18 Aug 2020 12:12:26

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 5'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:01:44', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '2cd97418-1506-4dbb-9a93-d9ebbf21519'	System	19 Aug 2020 13:05:13
User entered 'None (1)'	System	19 Aug 2020 13:05:13

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:01:47', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '2cd97418-1506-4dbb-9a93-d9ebbf21519'	System	19 Aug 2020 13:05:13
User entered 'No (N)'	System	19 Aug 2020 13:05:13

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:01:49', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '2cd97418-1506-4dbb-9a93-d9ebbf21519'	System	19 Aug 2020 13:05:13
User entered 'No (N)'	System	19 Aug 2020 13:05:13

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:01:53', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '2cd97418-1506-4dbb-9a93-d9ebbf21519'	System	19 Aug 2020 13:05:13
User entered 'None (1)'	System	19 Aug 2020 13:05:13

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:01:58', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '2cd97418-1506-4dbb-9a93-d9ebbf21519' User entered '19 Aug 2020 09:01'	System	19 Aug 2020 13:05:13
	System	19 Aug 2020 13:05:13

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 6'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:30', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '97302b69-8846-4f0c-a3ee-0625ce496558'	System	20 Aug 2020 12:16:49
User entered 'None (1)'	System	20 Aug 2020 12:16:49

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:35', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '97302b69-8846-4f0c-a3ee-0625ce496558'	System	20 Aug 2020 12:16:49
User entered 'No (N)'	System	20 Aug 2020 12:16:49

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:38', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '97302b69-8846-4f0c-a3ee-0625ce496558' User entered 'No (N)'	System	20 Aug 2020 12:16:49
	System	20 Aug 2020 12:16:49

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:42', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '97302b69-8846-4f0c-a3ee-0625ce496558'	System	20 Aug 2020 12:16:49
User entered 'None (1)'	System	20 Aug 2020 12:16:49

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:48', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '97302b69-8846-4f0c-a3ee-0625ce496558' User entered '20 Aug 2020 08:16'	System	20 Aug 2020 12:16:49
	System	20 Aug 2020 12:16:49

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 7'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:06:43', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '89cd98a0-21d5-48da-97d9-3d7d5f095b31' User entered 'None (1)'	System	21 Aug 2020 13:07:02
	System	21 Aug 2020 13:07:02

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:06:46', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '89cd98a0-21d5-48da-97d9-3d7d5f095b31' User entered 'No (N)'	System	21 Aug 2020 13:07:02
	System	21 Aug 2020 13:07:02

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:06:50', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '89cd98a0-21d5-48da-97d9-3d7d5f095b31' User entered 'No (N)'	System	21 Aug 2020 13:07:02
	System	21 Aug 2020 13:07:02

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:06:53', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '89cd98a0-21d5-48da-97d9-3d7d5f095b31' User entered 'None (1)'	System	21 Aug 2020 13:07:02
	System	21 Aug 2020 13:07:02

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:06:58', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '89cd98a0-21d5-48da-97d9-3d7d5f095b31'	System	21 Aug 2020 13:07:02
User entered '21 Aug 2020 09:06'	System	21 Aug 2020 13:07:02

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:14:47', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c4e635c7-c7d2-4e61-bc35-3fbd4e24d83e' User entered 'None (0)'	System	14 Aug 2020 21:15:25
	System	14 Aug 2020 21:15:25

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:14:52', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c4e635c7-c7d2-4e61-bc35-3fbd4e24d83e' User entered 'None (0)'	System	14 Aug 2020 21:15:25
	System	14 Aug 2020 21:15:25

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:14:56', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c4e635c7-c7d2-4e61-bc35-3fbd4e24d83e' User entered 'None (0)'	System	14 Aug 2020 21:15:25
	System	14 Aug 2020 21:15:25

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:15:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c4e635c7-c7d2-4e61-bc35-3fbd4e24d83e' User entered 'None (0)'	System	14 Aug 2020 21:15:25
	System	14 Aug 2020 21:15:25

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:15:04', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c4e635c7-c7d2-4e61-bc35-3fbd4e24d83e' User entered 'None (0)'	System	14 Aug 2020 21:15:25
	System	14 Aug 2020 21:15:25

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:15:07', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c4e635c7-c7d2-4e61-bc35-3fbd4e24d83e' User entered 'None (0)'	System	14 Aug 2020 21:15:25
	System	14 Aug 2020 21:15:25

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:15:15', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c4e635c7-c7d2-4e61-bc35-3fbd4e24d83e' User entered 'No (N)'	System	14 Aug 2020 21:15:25
	System	14 Aug 2020 21:15:25

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-14T17:15:21', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c4e635c7-c7d2-4e61-bc35-3fbd4e24d83e'	System	14 Aug 2020 21:15:25
User entered '14 Aug 2020 17:15'	System	14 Aug 2020 21:15:25

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '14 Aug 2020 16:44'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '14 Aug 2020 19:14'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:35:37', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1e283f16-0b63-411b-a571-1e042c130bf6' User entered 'None (0)'	System	15 Aug 2020 14:36:13
	System	15 Aug 2020 14:36:13

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:35:41', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1e283f16-0b63-411b-a571-1e042c130bf6' User entered 'None (0)'	System	15 Aug 2020 14:36:13
	System	15 Aug 2020 14:36:13

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:35:47', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1e283f16-0b63-411b-a571-1e042c130bf6' User entered 'None (0)'	System	15 Aug 2020 14:36:13
	System	15 Aug 2020 14:36:13

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:35:52', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1e283f16-0b63-411b-a571-1e042c130bf6' User entered 'None (0)'	System	15 Aug 2020 14:36:13
	System	15 Aug 2020 14:36:13

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:35:55', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1e283f16-0b63-411b-a571-1e042c130bf6' User entered 'None (0)'	System	15 Aug 2020 14:36:13
	System	15 Aug 2020 14:36:13

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:35:58', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1e283f16-0b63-411b-a571-1e042c130bf6' User entered 'None (0)'	System	15 Aug 2020 14:36:13
	System	15 Aug 2020 14:36:13

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:36:04', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1e283f16-0b63-411b-a571-1e042c130bf6' User entered 'No (N)'	System	15 Aug 2020 14:36:13
	System	15 Aug 2020 14:36:13

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-15T10:36:10', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1e283f16-0b63-411b-a571-1e042c130bf6' User entered '15 Aug 2020 10:36'	System	15 Aug 2020 14:36:13
	System	15 Aug 2020 14:36:13

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '14 Aug 2020 20:09'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 2'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:01:24', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '293b3cc6-18f2-4a49-aec0-4e1d8815c8de' User entered 'None (0)'	System	16 Aug 2020 13:01:56
	System	16 Aug 2020 13:01:56

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:01:27', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '293b3cc6-18f2-4a49-aec0-4e1d8815c8de' User entered 'None (0)'	System	16 Aug 2020 13:01:56
	System	16 Aug 2020 13:01:56

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:01:32', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '293b3cc6-18f2-4a49-aec0-4e1d8815c8de' User entered 'None (0)'	System	16 Aug 2020 13:01:56
	System	16 Aug 2020 13:01:56

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:01:35', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '293b3cc6-18f2-4a49-aec0-4e1d8815c8de' User entered 'None (0)'	System	16 Aug 2020 13:01:56
	System	16 Aug 2020 13:01:56

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:01:38', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '293b3cc6-18f2-4a49-aec0-4e1d8815c8de' User entered 'None (0)'	System	16 Aug 2020 13:01:56
	System	16 Aug 2020 13:01:56

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:01:41', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '293b3cc6-18f2-4a49-aec0-4e1d8815c8de' User entered 'None (0)'	System	16 Aug 2020 13:01:56
	System	16 Aug 2020 13:01:56

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:01:46', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '293b3cc6-18f2-4a49-aec0-4e1d8815c8de' User entered 'No (N)'	System	16 Aug 2020 13:01:56
	System	16 Aug 2020 13:01:56

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-16T09:01:55', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '293b3cc6-18f2-4a49-aec0-4e1d8815c8de' User entered '16 Aug 2020 09:01'	System	16 Aug 2020 13:01:56
	System	16 Aug 2020 13:01:56

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 3'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:00:57', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6ef733dc-7a4e-4b93-93f5-220116ceca2a' User entered 'None (0)'	System	17 Aug 2020 13:01:31
	System	17 Aug 2020 13:01:31

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:01:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6ef733dc-7a4e-4b93-93f5-220116ceca2a' User entered 'None (0)'	System	17 Aug 2020 13:01:31
	System	17 Aug 2020 13:01:31

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:01:06', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6ef733dc-7a4e-4b93-93f5-220116ceca2a' User entered 'None (0)'	System	17 Aug 2020 13:01:31
	System	17 Aug 2020 13:01:31

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:01:16', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6ef733dc-7a4e-4b93-93f5-220116ceca2a' User entered 'None (0)'	System	17 Aug 2020 13:01:31
	System	17 Aug 2020 13:01:31

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:01:19', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6ef733dc-7a4e-4b93-93f5-220116ceca2a' User entered 'None (0)'	System	17 Aug 2020 13:01:31
	System	17 Aug 2020 13:01:31

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:01:21', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6ef733dc-7a4e-4b93-93f5-220116ceca2a' User entered 'None (0)'	System	17 Aug 2020 13:01:31
	System	17 Aug 2020 13:01:31

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:01:25', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6ef733dc-7a4e-4b93-93f5-220116ceca2a' User entered 'No (N)'	System	17 Aug 2020 13:01:31
	System	17 Aug 2020 13:01:31

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-17T09:01:30', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6ef733dc-7a4e-4b93-93f5-220116ceca2a' User entered '17 Aug 2020 09:01'	System	17 Aug 2020 13:01:31
	System	17 Aug 2020 13:01:31

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 4'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:28', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a55e920e-c8c3-4082-ae97-12c6345abffe' User entered 'None (0)'	System	18 Aug 2020 12:12:52
	System	18 Aug 2020 12:12:52

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:30', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a55e920e-c8c3-4082-ae97-12c6345abffe' User entered 'None (0)'	System	18 Aug 2020 12:12:52
	System	18 Aug 2020 12:12:52

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:33', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a55e920e-c8c3-4082-ae97-12c6345abffe' User entered 'None (0)'	System	18 Aug 2020 12:12:52
	System	18 Aug 2020 12:12:52

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:36', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a55e920e-c8c3-4082-ae97-12c6345abffe' User entered 'None (0)'	System	18 Aug 2020 12:12:52
	System	18 Aug 2020 12:12:52

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:38', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a55e920e-c8c3-4082-ae97-12c6345abffe' User entered 'None (0)'	System	18 Aug 2020 12:12:52
	System	18 Aug 2020 12:12:52

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:41', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a55e920e-c8c3-4082-ae97-12c6345abffe' User entered 'None (0)'	System	18 Aug 2020 12:12:52
	System	18 Aug 2020 12:12:52

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:44', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a55e920e-c8c3-4082-ae97-12c6345abffe'	System	18 Aug 2020 12:12:52
User entered 'No (N)'	System	18 Aug 2020 12:12:52

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-18T08:12:50', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a55e920e-c8c3-4082-ae97-12c6345abffe' User entered '18 Aug 2020 08:12'	System	18 Aug 2020 12:12:52
	System	18 Aug 2020 12:12:52

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 5'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:02:05', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c1b09185-fe73-4986-bd1b-070089d8ab3f' User entered 'None (0)'	System	19 Aug 2020 13:05:22
	System	19 Aug 2020 13:05:22

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:02:08', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c1b09185-fe73-4986-bd1b-070089d8ab3f' User entered 'None (0)'	System	19 Aug 2020 13:05:22
	System	19 Aug 2020 13:05:22

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:02:11', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c1b09185-fe73-4986-bd1b-070089d8ab3f' User entered 'None (0)'	System	19 Aug 2020 13:05:22
	System	19 Aug 2020 13:05:22

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:02:15', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c1b09185-fe73-4986-bd1b-070089d8ab3f' User entered 'None (0)'	System	19 Aug 2020 13:05:22
	System	19 Aug 2020 13:05:22

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:02:17', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c1b09185-fe73-4986-bd1b-070089d8ab3f' User entered 'None (0)'	System	19 Aug 2020 13:05:22
	System	19 Aug 2020 13:05:22

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:02:20', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c1b09185-fe73-4986-bd1b-070089d8ab3f' User entered 'None (0)'	System	19 Aug 2020 13:05:22
	System	19 Aug 2020 13:05:22

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:02:23', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c1b09185-fe73-4986-bd1b-070089d8ab3f' User entered 'No (N)'	System	19 Aug 2020 13:05:22
	System	19 Aug 2020 13:05:22

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-19T09:02:28', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'c1b09185-fe73-4986-bd1b-070089d8ab3f' User entered '19 Aug 2020 09:02'	System	19 Aug 2020 13:05:22
	System	19 Aug 2020 13:05:22

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 6'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:55', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ebb32603-e695-4f69-b513-c12a36ad85a2' User entered 'None (0)'	System	20 Aug 2020 12:17:30
	System	20 Aug 2020 12:17:30

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:16:58', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ebb32603-e695-4f69-b513-c12a36ad85a2' User entered 'None (0)'	System	20 Aug 2020 12:17:30
	System	20 Aug 2020 12:17:30

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:17:02', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ebb32603-e695-4f69-b513-c12a36ad85a2' User entered 'None (0)'	System	20 Aug 2020 12:17:30
	System	20 Aug 2020 12:17:30

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:17:06', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ebb32603-e695-4f69-b513-c12a36ad85a2' User entered 'None (0)'	System	20 Aug 2020 12:17:30
	System	20 Aug 2020 12:17:30

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:17:10', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ebb32603-e695-4f69-b513-c12a36ad85a2' User entered 'None (0)'	System	20 Aug 2020 12:17:30
	System	20 Aug 2020 12:17:30

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:17:13', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ebb32603-e695-4f69-b513-c12a36ad85a2' User entered 'None (0)'	System	20 Aug 2020 12:17:30
	System	20 Aug 2020 12:17:30

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:17:16', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ebb32603-e695-4f69-b513-c12a36ad85a2' User entered 'No (N)'	System	20 Aug 2020 12:17:30
	System	20 Aug 2020 12:17:30

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-20T08:17:24', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ebb32603-e695-4f69-b513-c12a36ad85a2' User entered '20 Aug 2020 08:17'	System	20 Aug 2020 12:17:30
	System	20 Aug 2020 12:17:30

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 7'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:07:04', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '973cd0c3-f0ab-4db1-9472-3e3803bf15be' User entered 'None (0)'	System	21 Aug 2020 13:07:35
	System	21 Aug 2020 13:07:35

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:07:07', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '973cd0c3-f0ab-4db1-9472-3e3803bf15be' User entered 'None (0)'	System	21 Aug 2020 13:07:35
	System	21 Aug 2020 13:07:35

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:07:15', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '973cd0c3-f0ab-4db1-9472-3e3803bf15be' User entered 'None (0)'	System	21 Aug 2020 13:07:35
	System	21 Aug 2020 13:07:35

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:07:19', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '973cd0c3-f0ab-4db1-9472-3e3803bf15be' User entered 'None (0)'	System	21 Aug 2020 13:07:35
	System	21 Aug 2020 13:07:35

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:07:22', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '973cd0c3-f0ab-4db1-9472-3e3803bf15be' User entered 'None (0)'	System	21 Aug 2020 13:07:35
	System	21 Aug 2020 13:07:35

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:07:24', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '973cd0c3-f0ab-4db1-9472-3e3803bf15be' User entered 'None (0)'	System	21 Aug 2020 13:07:35
	System	21 Aug 2020 13:07:35

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:07:27', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '973cd0c3-f0ab-4db1-9472-3e3803bf15be' User entered 'No (N)'	System	21 Aug 2020 13:07:35
	System	21 Aug 2020 13:07:35

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-08-21T09:07:32', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '973cd0c3-f0ab-4db1-9472-3e3803bf15be' User entered '21 Aug 2020 09:07'	System	21 Aug 2020 13:07:35
	System	21 Aug 2020 13:07:35

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:31:21

US3372137

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 19:45:27

US3372137

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '21 Aug 2020'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 19:45:27

US3372137

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 19:45:27

US3372137

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	21 Aug 2020 19:45:27

US3372137

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 19:45:30

US3372137

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User entered 'I'	System	21 Aug 2020 19:45:30

US3372137

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	04 Sep 2020 14:53:49

US3372137

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '30 Aug 2020'	(b) (4) Alexandra Arango (b) (4)	04 Sep 2020 14:53:49

US3372137

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	04 Sep 2020 14:53:49

US3372137

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Alexandra Arango (b) (4)	04 Sep 2020 14:53:49
	(b) (4)	

US3372137

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	04 Sep 2020 14:53:55

US3372137

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User entered 'I'	System	04 Sep 2020 14:53:55

US3372137

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 14:12:34

US3372137

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '4 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 14:12:34

US3372137

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 14:12:34

US3372137

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 14:12:34
	(b) (4)	

US3372137

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 14:12:38

US3372137

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User entered 'I'	System	07 Sep 2020 14:12:38

US3372137

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:10

US3372137

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:10

US3372137

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:10

US3372137

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'VISIT2'	System	15 Sep 2020 20:34:10

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '15:15'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '15 Sep 2020 15:15'	System	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '53'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'bpm'	System	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'breaths/min'	System	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '145'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'mmHg'	System	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '81' reason for change: Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	24 Sep 2020 21:28:04
User entered '91'	(b) (4)	
	Peter Jacob (b) (4)	24 Sep 2020 21:27:58
	(b) (4)	

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'mmHg'	System	24 Sep 2020 21:27:58

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '16:56'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '15 Sep 2020 16:56'	System	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '36.3' C	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '72'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'bpm'	System	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '14'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'breaths/min'	System	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '153'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'mmHg'	System	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '92'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'mmHg'	System	24 Sep 2020 21:28:24

US3372137

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 21:28:30

US3372137

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:30

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:02

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:02

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

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 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:02

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 20:36:02

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:02

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '16:16'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:02

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '15 Sep 2020 16:16'	System	15 Sep 2020 20:36:02

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:02

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'ONCE'	System	15 Sep 2020 20:36:02

US3372137

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 20:36:02

US3372137

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 21:28:38

US3372137

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:38

US3372137

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '15:38'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:38

US3372137

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '15 Sep 2020 15:38'	System	24 Sep 2020 21:28:38

US3372137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:13:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:46

US3372137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:46

US3372137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 21:28:46

US3372137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '15:37'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:46

US3372137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:13:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '15 Sep 2020 15:37'	System	24 Sep 2020 21:28:46

US3372137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:46

US3372137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 21:28:46

US3372137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:46

US3372137

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:13:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered empty.	System	24 Sep 2020 21:28:46

US3372137

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 21:28:49

US3372137

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'I'	System	24 Sep 2020 21:28:49

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:03:18', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '38a5b5bb-2081-4bf6-90d3-51e582075a9c' User entered 'Yes (Y)'	System	15 Sep 2020 21:03:42
	System	15 Sep 2020 21:03:42

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:03:25', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '38a5b5bb-2081-4bf6-90d3-51e582075a9c' User entered '97.4'	System	15 Sep 2020 21:03:42
	System	15 Sep 2020 21:03:42

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:03:31', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '38a5b5bb-2081-4bf6-90d3-51e582075a9c' User entered 'No (N)'	System	15 Sep 2020 21:03:42
	System	15 Sep 2020 21:03:42

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:03:39', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '38a5b5bb-2081-4bf6-90d3-51e582075a9c' User entered '15 Sep 2020 17:03'	System	15 Sep 2020 21:03:42
	System	15 Sep 2020 21:03:42

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Sep 2020 16:36'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Sep 2020 19:06'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:51:39', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'effd08d4-93d6-4f22-9da0-210a2a1056e2'	System	16 Sep 2020 10:52:01
User entered 'Yes (Y)'	System	16 Sep 2020 10:52:01

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:51:46', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'effd08d4-93d6-4f22-9da0-210a2a1056e2' User entered '98.4'	System	16 Sep 2020 10:52:01
	System	16 Sep 2020 10:52:01

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:51:50', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'effd08d4-93d6-4f22-9da0-210a2a1056e2'	System	16 Sep 2020 10:52:01
User entered 'No (N)'	System	16 Sep 2020 10:52:01

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:51:58', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'effd08d4-93d6-4f22-9da0-210a2a1056e2'	System	16 Sep 2020 10:52:01
User entered '16 Sep 2020 06:51'	System	16 Sep 2020 10:52:01

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Sep 2020 20:01'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 2'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:45:58', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '4ebaa3d8-c527-4143-9832-c367b60a8126' User entered 'Yes (Y)'	System	17 Sep 2020 10:46:16
	System	17 Sep 2020 10:46:16

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:04', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '4ebaa3d8-c527-4143-9832-c367b60a8126' User entered '97.7'	System	17 Sep 2020 10:46:16
	System	17 Sep 2020 10:46:16

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:07', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '4ebaa3d8-c527-4143-9832-c367b60a8126'	System	17 Sep 2020 10:46:16
User entered 'No (N)'	System	17 Sep 2020 10:46:16

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:12', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '4ebaa3d8-c527-4143-9832-c367b60a8126' User entered '17 Sep 2020 06:46'	System	17 Sep 2020 10:46:16
	System	17 Sep 2020 10:46:16

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 3'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:01:50', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '4aee53b3-94a6-4ac3-9206-43f5e0b594a0' User entered 'Yes (Y)'	System	18 Sep 2020 11:02:37
	System	18 Sep 2020 11:02:37

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:01:55', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '4aee53b3-94a6-4ac3-9206-43f5e0b594a0' User entered '97.3'	System	18 Sep 2020 11:02:37
	System	18 Sep 2020 11:02:37

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:01:59', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '4aee53b3-94a6-4ac3-9206-43f5e0b594a0' User entered 'No (N)'	System	18 Sep 2020 11:02:37
	System	18 Sep 2020 11:02:37

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:03', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '4aee53b3-94a6-4ac3-9206-43f5e0b594a0' User entered '18 Sep 2020 07:02'	System	18 Sep 2020 11:02:37
	System	18 Sep 2020 11:02:37

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 4'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:58:04', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '73cea0c3-e10f-4617-ba31-e66f3f2eacc6' User entered 'Yes (Y)'	System	19 Sep 2020 11:58:24
	System	19 Sep 2020 11:58:24

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:58:12', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '73cea0c3-e10f-4617-ba31-e66f3f2eacc6' User entered '97.4'	System	19 Sep 2020 11:58:24
	System	19 Sep 2020 11:58:24

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:58:17', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '73cea0c3-e10f-4617-ba31-e66f3f2eacc6'	System	19 Sep 2020 11:58:24
User entered 'No (N)'	System	19 Sep 2020 11:58:24

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:58:22', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '73cea0c3-e10f-4617-ba31-e66f3f2eacc6' User entered '19 Sep 2020 07:58'	System	19 Sep 2020 11:58:24
	System	19 Sep 2020 11:58:24

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 5'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:05', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '31608b7a-b80e-456e-8ea6-527fd5e06aad' User entered 'Yes (Y)'	System	20 Sep 2020 09:38:25
	System	20 Sep 2020 09:38:25

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:11', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '31608b7a-b80e-456e-8ea6-527fd5e06aad' User entered '98.2'	System	20 Sep 2020 09:38:25
	System	20 Sep 2020 09:38:25

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:19', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '31608b7a-b80e-456e-8ea6-527fd5e06aad'	System	20 Sep 2020 09:38:25
User entered 'No (N)'	System	20 Sep 2020 09:38:25

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:23', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '31608b7a-b80e-456e-8ea6-527fd5e06aad' User entered '20 Sep 2020 05:38'	System	20 Sep 2020 09:38:25
	System	20 Sep 2020 09:38:25

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 6'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:30:46', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'bb5ce2cd-6be4-4a77-94ad-871d5f8a5c2e' User entered 'Yes (Y)'	System	21 Sep 2020 10:31:02
	System	21 Sep 2020 10:31:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:30:51', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'bb5ce2cd-6be4-4a77-94ad-871d5f8a5c2e' User entered '97.2'	System	21 Sep 2020 10:31:02
	System	21 Sep 2020 10:31:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:30:54', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'bb5ce2cd-6be4-4a77-94ad-871d5f8a5c2e' User entered 'No (N)'	System	21 Sep 2020 10:31:02
	System	21 Sep 2020 10:31:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:30:58', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'bb5ce2cd-6be4-4a77-94ad-871d5f8a5c2e' User entered '21 Sep 2020 06:30'	System	21 Sep 2020 10:31:02
	System	21 Sep 2020 10:31:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 7'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:45:25', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6f75799f-8a38-4e9c-b2ec-610502f5d26e' User entered 'Yes (Y)'	System	22 Sep 2020 10:45:46
	System	22 Sep 2020 10:45:46

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:45:30', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6f75799f-8a38-4e9c-b2ec-610502f5d26e' User entered '97.6'	System	22 Sep 2020 10:45:46
	System	22 Sep 2020 10:45:46

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:45:34', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6f75799f-8a38-4e9c-b2ec-610502f5d26e'	System	22 Sep 2020 10:45:46
User entered 'No (N)'	System	22 Sep 2020 10:45:46

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:45:40', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6f75799f-8a38-4e9c-b2ec-610502f5d26e' User entered '22 Sep 2020 06:45'	System	22 Sep 2020 10:45:46
	System	22 Sep 2020 10:45:46

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:03:53', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a512507c-869f-4ba2-b900-78b92ddae185'	System	15 Sep 2020 21:04:22
User entered 'None (1)'	System	15 Sep 2020 21:04:22

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:03', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a512507c-869f-4ba2-b900-78b92ddae185' User entered 'No (N)'	System	15 Sep 2020 21:04:22
	System	15 Sep 2020 21:04:22

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:11', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a512507c-869f-4ba2-b900-78b92ddae185' User entered 'No (N)'	System	15 Sep 2020 21:04:22
	System	15 Sep 2020 21:04:22

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:14', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a512507c-869f-4ba2-b900-78b92ddae185'	System	15 Sep 2020 21:04:22
User entered 'None (1)'	System	15 Sep 2020 21:04:22

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:20', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a512507c-869f-4ba2-b900-78b92ddae185' User entered '15 Sep 2020 17:04'	System	15 Sep 2020 21:04:22
	System	15 Sep 2020 21:04:22

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Sep 2020 16:36'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Sep 2020 19:06'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:07', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '29779c52-7f4d-4cf4-8b83-1c7213a81303'	System	16 Sep 2020 10:52:37
User entered 'None (1)'	System	16 Sep 2020 10:52:37

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:10', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '29779c52-7f4d-4cf4-8b83-1c7213a81303'	System	16 Sep 2020 10:52:37
User entered 'No (N)'	System	16 Sep 2020 10:52:37

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:15', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '29779c52-7f4d-4cf4-8b83-1c7213a81303'	System	16 Sep 2020 10:52:37
User entered 'No (N)'	System	16 Sep 2020 10:52:37

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:25', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '29779c52-7f4d-4cf4-8b83-1c7213a81303'	System	16 Sep 2020 10:52:37
User entered 'None (1)'	System	16 Sep 2020 10:52:37

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:29', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '29779c52-7f4d-4cf4-8b83-1c7213a81303'	System	16 Sep 2020 10:52:37
User entered '16 Sep 2020 06:52'	System	16 Sep 2020 10:52:37

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Sep 2020 20:01'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 2'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:20', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '26856966-7372-4557-b5e0-86827b512f57'	System	17 Sep 2020 10:46:49
User entered 'None (1)'	System	17 Sep 2020 10:46:49

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:26', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '26856966-7372-4557-b5e0-86827b512f57'	System	17 Sep 2020 10:46:49
User entered 'No (N)'	System	17 Sep 2020 10:46:49

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:31', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '26856966-7372-4557-b5e0-86827b512f57'	System	17 Sep 2020 10:46:49
User entered 'No (N)'	System	17 Sep 2020 10:46:49

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:41', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '26856966-7372-4557-b5e0-86827b512f57'	System	17 Sep 2020 10:46:49
User entered 'None (1)'	System	17 Sep 2020 10:46:49

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:47', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '26856966-7372-4557-b5e0-86827b512f57'	System	17 Sep 2020 10:46:49
User entered '17 Sep 2020 06:46'	System	17 Sep 2020 10:46:49

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 3'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:08', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '457af741-72c1-43d5-8eff-6df958c1b683'	System	18 Sep 2020 11:02:41
User entered 'None (1)'	System	18 Sep 2020 11:02:41

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:12', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '457af741-72c1-43d5-8eff-6df958c1b683'	System	18 Sep 2020 11:02:41
User entered 'No (N)'	System	18 Sep 2020 11:02:41

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:15', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '457af741-72c1-43d5-8eff-6df958c1b683'	System	18 Sep 2020 11:02:41
User entered 'No (N)'	System	18 Sep 2020 11:02:41

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:18', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '457af741-72c1-43d5-8eff-6df958c1b683'	System	18 Sep 2020 11:02:41
User entered 'None (1)'	System	18 Sep 2020 11:02:41

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:23', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '457af741-72c1-43d5-8eff-6df958c1b683' User entered '18 Sep 2020 07:02'	System	18 Sep 2020 11:02:41
	System	18 Sep 2020 11:02:41

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 4'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:58:29', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '85539763-72ff-4991-b65e-9fd905bac98e'	System	19 Sep 2020 11:59:00
User entered 'None (1)'	System	19 Sep 2020 11:59:00

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:58:33', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '85539763-72ff-4991-b65e-9fd905bac98e'	System	19 Sep 2020 11:59:00
User entered 'No (N)'	System	19 Sep 2020 11:59:00

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:58:38', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '85539763-72ff-4991-b65e-9fd905bac98e' User entered 'No (N)'	System	19 Sep 2020 11:59:00
	System	19 Sep 2020 11:59:00

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:58:43', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '85539763-72ff-4991-b65e-9fd905bac98e' User entered 'None (1)'	System	19 Sep 2020 11:59:00
	System	19 Sep 2020 11:59:00

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:58:58', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '85539763-72ff-4991-b65e-9fd905bac98e' User entered '19 Sep 2020 07:58'	System	19 Sep 2020 11:59:00
	System	19 Sep 2020 11:59:00

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 5'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:28', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'd96df3e8-0fac-4e54-b385-95795b8255ea' User entered 'None (1)'	System	20 Sep 2020 09:38:46
	System	20 Sep 2020 09:38:46

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:32', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'd96df3e8-0fac-4e54-b385-95795b8255ea' User entered 'No (N)'	System	20 Sep 2020 09:38:46
	System	20 Sep 2020 09:38:46

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:35', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'd96df3e8-0fac-4e54-b385-95795b8255ea' User entered 'No (N)'	System	20 Sep 2020 09:38:46
	System	20 Sep 2020 09:38:46

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:38', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'd96df3e8-0fac-4e54-b385-95795b8255ea' User entered 'None (1)'	System	20 Sep 2020 09:38:46
	System	20 Sep 2020 09:38:46

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:42', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'd96df3e8-0fac-4e54-b385-95795b8255ea' User entered '20 Sep 2020 05:38'	System	20 Sep 2020 09:38:46
	System	20 Sep 2020 09:38:46

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 6'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:05', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5a6a1be8-95d7-4b6a-8c89-cd986df80044'	System	21 Sep 2020 10:31:23
User entered 'None (1)'	System	21 Sep 2020 10:31:23

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:10', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5a6a1be8-95d7-4b6a-8c89-cd986df80044' User entered 'No (N)'	System	21 Sep 2020 10:31:23
	System	21 Sep 2020 10:31:23

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:13', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5a6a1be8-95d7-4b6a-8c89-cd986df80044' User entered 'No (N)'	System	21 Sep 2020 10:31:23
	System	21 Sep 2020 10:31:23

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:18', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5a6a1be8-95d7-4b6a-8c89-cd986df80044'	System	21 Sep 2020 10:31:23
User entered 'None (1)'	System	21 Sep 2020 10:31:23

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:22', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5a6a1be8-95d7-4b6a-8c89-cd986df80044' User entered '21 Sep 2020 06:31'	System	21 Sep 2020 10:31:23
	System	21 Sep 2020 10:31:23

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 7'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:45:50', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '9a7c4e24-f27d-4520-8ebf-05fe34934e14'	System	22 Sep 2020 10:46:10
User entered 'None (1)'	System	22 Sep 2020 10:46:10

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:45:54', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '9a7c4e24-f27d-4520-8ebf-05fe34934e14'	System	22 Sep 2020 10:46:10
User entered 'No (N)'	System	22 Sep 2020 10:46:10

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '9a7c4e24-f27d-4520-8ebf-05fe34934e14'	System	22 Sep 2020 10:46:10
User entered 'No (N)'	System	22 Sep 2020 10:46:10

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:03', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '9a7c4e24-f27d-4520-8ebf-05fe34934e14'	System	22 Sep 2020 10:46:10
User entered 'None (1)'	System	22 Sep 2020 10:46:10

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:06', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '9a7c4e24-f27d-4520-8ebf-05fe34934e14'	System	22 Sep 2020 10:46:10
User entered '22 Sep 2020 06:46'	System	22 Sep 2020 10:46:10

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:25', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '69bf4c7c-b037-4259-855d-23eeaa4bf75a' User entered 'None (0)'	System	15 Sep 2020 21:05:03
	System	15 Sep 2020 21:05:03

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:28', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '69bf4c7c-b037-4259-855d-23eeaa4bf75a' User entered 'None (0)'	System	15 Sep 2020 21:05:03
	System	15 Sep 2020 21:05:03

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:31', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '69bf4c7c-b037-4259-855d-23eeaa4bf75a' User entered 'None (0)'	System	15 Sep 2020 21:05:03
	System	15 Sep 2020 21:05:03

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:42', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '69bf4c7c-b037-4259-855d-23eeaa4bf75a'	System	15 Sep 2020 21:05:03
User entered 'No interference with activity (1)'	System	15 Sep 2020 21:05:03

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '69bf4c7c-b037-4259-855d-23eeaa4bf75a' User entered 'None (0)'	System	15 Sep 2020 21:05:03
	System	15 Sep 2020 21:05:03

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:48', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '69bf4c7c-b037-4259-855d-23eeaa4bf75a' User entered 'None (0)'	System	15 Sep 2020 21:05:03
	System	15 Sep 2020 21:05:03

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:04:52', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '69bf4c7c-b037-4259-855d-23eeaa4bf75a' User entered 'No (N)'	System	15 Sep 2020 21:05:03
	System	15 Sep 2020 21:05:03

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-15T17:05:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '69bf4c7c-b037-4259-855d-23eeaa4bf75a'	System	15 Sep 2020 21:05:03
User entered '15 Sep 2020 17:05'	System	15 Sep 2020 21:05:03

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Sep 2020 16:36'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Sep 2020 19:06'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:33', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'fd39d796-734b-4be9-9314-2e134f5eb889' User entered 'None (0)'	System	16 Sep 2020 10:53:04
	System	16 Sep 2020 10:53:04

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:36', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'fd39d796-734b-4be9-9314-2e134f5eb889' User entered 'None (0)'	System	16 Sep 2020 10:53:04
	System	16 Sep 2020 10:53:04

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:38', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'fd39d796-734b-4be9-9314-2e134f5eb889' User entered 'None (0)'	System	16 Sep 2020 10:53:04
	System	16 Sep 2020 10:53:04

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:42', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'fd39d796-734b-4be9-9314-2e134f5eb889' User entered 'None (0)'	System	16 Sep 2020 10:53:04
	System	16 Sep 2020 10:53:04

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:49', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'fd39d796-734b-4be9-9314-2e134f5eb889' User entered 'None (0)'	System	16 Sep 2020 10:53:04
	System	16 Sep 2020 10:53:04

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:52', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'fd39d796-734b-4be9-9314-2e134f5eb889' User entered 'None (0)'	System	16 Sep 2020 10:53:04
	System	16 Sep 2020 10:53:04

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:56', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'fd39d796-734b-4be9-9314-2e134f5eb889'	System	16 Sep 2020 10:53:04
User entered 'No (N)'	System	16 Sep 2020 10:53:04

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-16T06:52:59', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'fd39d796-734b-4be9-9314-2e134f5eb889'	System	16 Sep 2020 10:53:04
User entered '16 Sep 2020 06:52'	System	16 Sep 2020 10:53:04

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '15 Sep 2020 20:01'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 2'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:53', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1b1840f5-536d-4b0c-97f5-a9a84af885f8' User entered 'None (0)'	System	17 Sep 2020 10:47:20
	System	17 Sep 2020 10:47:20

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:56', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1b1840f5-536d-4b0c-97f5-a9a84af885f8' User entered 'None (0)'	System	17 Sep 2020 10:47:20
	System	17 Sep 2020 10:47:20

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:46:58', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1b1840f5-536d-4b0c-97f5-a9a84af885f8' User entered 'None (0)'	System	17 Sep 2020 10:47:20
	System	17 Sep 2020 10:47:20

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:47:02', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1b1840f5-536d-4b0c-97f5-a9a84af885f8' User entered 'None (0)'	System	17 Sep 2020 10:47:20
	System	17 Sep 2020 10:47:20

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:47:07', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1b1840f5-536d-4b0c-97f5-a9a84af885f8' User entered 'None (0)'	System	17 Sep 2020 10:47:20
	System	17 Sep 2020 10:47:20

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:47:10', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1b1840f5-536d-4b0c-97f5-a9a84af885f8' User entered 'None (0)'	System	17 Sep 2020 10:47:20
	System	17 Sep 2020 10:47:20

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:47:14', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1b1840f5-536d-4b0c-97f5-a9a84af885f8'	System	17 Sep 2020 10:47:20
User entered 'No (N)'	System	17 Sep 2020 10:47:20

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-17T06:47:17', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1b1840f5-536d-4b0c-97f5-a9a84af885f8' User entered '17 Sep 2020 06:47'	System	17 Sep 2020 10:47:20
	System	17 Sep 2020 10:47:20

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 3'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:27', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede4ea5e-b579-4085-88a9-855358d5916b' User entered 'None (0)'	System	18 Sep 2020 11:02:53
	System	18 Sep 2020 11:02:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:31', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede4ea5e-b579-4085-88a9-855358d5916b' User entered 'None (0)'	System	18 Sep 2020 11:02:53
	System	18 Sep 2020 11:02:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:34', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede4ea5e-b579-4085-88a9-855358d5916b' User entered 'None (0)'	System	18 Sep 2020 11:02:53
	System	18 Sep 2020 11:02:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:36', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede4ea5e-b579-4085-88a9-855358d5916b' User entered 'None (0)'	System	18 Sep 2020 11:02:53
	System	18 Sep 2020 11:02:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:38', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede4ea5e-b579-4085-88a9-855358d5916b' User entered 'None (0)'	System	18 Sep 2020 11:02:53
	System	18 Sep 2020 11:02:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:41', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede4ea5e-b579-4085-88a9-855358d5916b' User entered 'None (0)'	System	18 Sep 2020 11:02:53
	System	18 Sep 2020 11:02:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede4ea5e-b579-4085-88a9-855358d5916b' User entered 'No (N)'	System	18 Sep 2020 11:02:53
	System	18 Sep 2020 11:02:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-18T07:02:48', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede4ea5e-b579-4085-88a9-855358d5916b' User entered '18 Sep 2020 07:02'	System	18 Sep 2020 11:02:53
	System	18 Sep 2020 11:02:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 4'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:59:08', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '109500f5-1438-40ac-82cb-c620908dbe8b' User entered 'None (0)'	System	19 Sep 2020 11:59:34
	System	19 Sep 2020 11:59:34

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:59:11', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '109500f5-1438-40ac-82cb-c620908dbe8b' User entered 'None (0)'	System	19 Sep 2020 11:59:34
	System	19 Sep 2020 11:59:34

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:59:14', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '109500f5-1438-40ac-82cb-c620908dbe8b' User entered 'None (0)'	System	19 Sep 2020 11:59:34
	System	19 Sep 2020 11:59:34

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:59:19', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '109500f5-1438-40ac-82cb-c620908dbe8b' User entered 'None (0)'	System	19 Sep 2020 11:59:34
	System	19 Sep 2020 11:59:34

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:59:22', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '109500f5-1438-40ac-82cb-c620908dbe8b' User entered 'None (0)'	System	19 Sep 2020 11:59:34
	System	19 Sep 2020 11:59:34

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:59:24', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '109500f5-1438-40ac-82cb-c620908dbe8b' User entered 'None (0)'	System	19 Sep 2020 11:59:34
	System	19 Sep 2020 11:59:34

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:59:29', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '109500f5-1438-40ac-82cb-c620908dbe8b' User entered 'No (N)'	System	19 Sep 2020 11:59:34
	System	19 Sep 2020 11:59:34

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-19T07:59:32', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '109500f5-1438-40ac-82cb-c620908dbe8b' User entered '19 Sep 2020 07:59'	System	19 Sep 2020 11:59:34
	System	19 Sep 2020 11:59:34

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 5'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:47', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede666a2-a2b6-44d3-8ca2-46ae8ccb910f' User entered 'None (0)'	System	20 Sep 2020 09:39:09
	System	20 Sep 2020 09:39:09

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:49', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede666a2-a2b6-44d3-8ca2-46ae8ccb910f' User entered 'None (0)'	System	20 Sep 2020 09:39:09
	System	20 Sep 2020 09:39:09

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:52', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede666a2-a2b6-44d3-8ca2-46ae8ccb910f' User entered 'None (0)'	System	20 Sep 2020 09:39:09
	System	20 Sep 2020 09:39:09

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:54', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede666a2-a2b6-44d3-8ca2-46ae8ccb910f' User entered 'None (0)'	System	20 Sep 2020 09:39:09
	System	20 Sep 2020 09:39:09

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:38:57', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede666a2-a2b6-44d3-8ca2-46ae8ccb910f' User entered 'None (0)'	System	20 Sep 2020 09:39:09
	System	20 Sep 2020 09:39:09

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:39:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede666a2-a2b6-44d3-8ca2-46ae8ccb910f' User entered 'None (0)'	System	20 Sep 2020 09:39:09
	System	20 Sep 2020 09:39:09

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:39:03', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede666a2-a2b6-44d3-8ca2-46ae8ccb910f' User entered 'No (N)'	System	20 Sep 2020 09:39:09
	System	20 Sep 2020 09:39:09

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-20T05:39:07', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'ede666a2-a2b6-44d3-8ca2-46ae8ccb910f' User entered '20 Sep 2020 05:39'	System	20 Sep 2020 09:39:09
	System	20 Sep 2020 09:39:09

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 6'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:26', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'cdd0d071-ab61-4286-a904-1f4418b28bf1' User entered 'None (0)'	System	21 Sep 2020 10:31:53
	System	21 Sep 2020 10:31:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:29', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'cdd0d071-ab61-4286-a904-1f4418b28bf1' User entered 'None (0)'	System	21 Sep 2020 10:31:53
	System	21 Sep 2020 10:31:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:32', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'cdd0d071-ab61-4286-a904-1f4418b28bf1' User entered 'None (0)'	System	21 Sep 2020 10:31:53
	System	21 Sep 2020 10:31:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:35', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'cdd0d071-ab61-4286-a904-1f4418b28bf1' User entered 'None (0)'	System	21 Sep 2020 10:31:53
	System	21 Sep 2020 10:31:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:38', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'cdd0d071-ab61-4286-a904-1f4418b28bf1' User entered 'None (0)'	System	21 Sep 2020 10:31:53
	System	21 Sep 2020 10:31:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:42', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'cdd0d071-ab61-4286-a904-1f4418b28bf1' User entered 'None (0)'	System	21 Sep 2020 10:31:53
	System	21 Sep 2020 10:31:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'cdd0d071-ab61-4286-a904-1f4418b28bf1' User entered 'No (N)'	System	21 Sep 2020 10:31:53
	System	21 Sep 2020 10:31:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-21T06:31:48', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'cdd0d071-ab61-4286-a904-1f4418b28bf1' User entered '21 Sep 2020 06:31'	System	21 Sep 2020 10:31:53
	System	21 Sep 2020 10:31:53

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	15 Sep 2020 20:36:02
User entered 'Day 7'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:11', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1ab667df-5a49-426f-ac6f-65956e5b6da3' User entered 'None (0)'	System	22 Sep 2020 10:46:56
	System	22 Sep 2020 10:46:56

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:13', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1ab667df-5a49-426f-ac6f-65956e5b6da3' User entered 'None (0)'	System	22 Sep 2020 10:46:56
	System	22 Sep 2020 10:46:56

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:16', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1ab667df-5a49-426f-ac6f-65956e5b6da3' User entered 'None (0)'	System	22 Sep 2020 10:46:56
	System	22 Sep 2020 10:46:56

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:23', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1ab667df-5a49-426f-ac6f-65956e5b6da3' User entered 'None (0)'	System	22 Sep 2020 10:46:56
	System	22 Sep 2020 10:46:56

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:28', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1ab667df-5a49-426f-ac6f-65956e5b6da3' User entered 'None (0)'	System	22 Sep 2020 10:46:56
	System	22 Sep 2020 10:46:56

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:33', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1ab667df-5a49-426f-ac6f-65956e5b6da3' User entered 'None (0)'	System	22 Sep 2020 10:46:56
	System	22 Sep 2020 10:46:56

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:52', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1ab667df-5a49-426f-ac6f-65956e5b6da3'	System	22 Sep 2020 10:46:56
User entered 'No (N)'	System	22 Sep 2020 10:46:56

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-09-22T06:46:55', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '1ab667df-5a49-426f-ac6f-65956e5b6da3'	System	22 Sep 2020 10:46:56
User entered '22 Sep 2020 06:46'	System	22 Sep 2020 10:46:56

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 20:36:02

US3372137

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:13:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 20:36:02

US3372137

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	01 Oct 2020 19:28:32

US3372137

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
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).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 10:11:35
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 'Phone visit completed within window per protocol' (Site from System).	Alexandra Arango (b) (4) (b) (4)	01 Oct 2020 19:28:37
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	01 Oct 2020 19:28:32
User entered '18 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	01 Oct 2020 19:28:32

US3372137

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	01 Oct 2020 19:28:32

US3372137

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Alexandra Arango (b) (4)	01 Oct 2020 19:28:32
	(b) (4)	

US3372137

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	01 Oct 2020 19:28:44

US3372137

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User entered 'I'	System	01 Oct 2020 19:28:44

US3372137

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	01 Oct 2020 19:29:09

US3372137

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
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).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 10:11:39
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.' answered with 'Phone visit completed within window per protocol' (Site from System).	Alexandra Arango (b) (4) (b) (4)	01 Oct 2020 19:29:12
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	01 Oct 2020 19:29:09
User entered '25 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	01 Oct 2020 19:29:09

US3372137

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	01 Oct 2020 19:29:09

US3372137

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Alexandra Arango (b) (4)	01 Oct 2020 19:29:09
	(b) (4)	

US3372137

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	01 Oct 2020 19:29:18

US3372137

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User entered 'I'	System	01 Oct 2020 19:29:18

US3372137

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Oct 2020 13:11:03

US3372137

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 07:38:06
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within window per protocol' (Site from System).	Alexandra Arango (b) (4) (b) (4)	03 Oct 2020 13:11:50
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Oct 2020 13:11:03
User entered '3 Oct 2020'	Alexandra Arango (b) (4) (b) (4)	03 Oct 2020 13:11:03

US3372137

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	03 Oct 2020 13:11:03

US3372137

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Alexandra Arango (b) (4)	03 Oct 2020 13:11:03
	(b) (4)	

US3372137

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Oct 2020 13:11:55

US3372137

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:06:59
User entered 'I'	System	03 Oct 2020 13:11:55

US3372137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 21 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 13:50:56
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 21 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:44:08
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 21 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:15:20
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 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)	24 Nov 2020 16:47:57

US3372137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 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 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Nov 2020 23:07:51
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 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) (b) (4)	22 Oct 2020 06:57:29
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	12 Oct 2020 13:13:57

US3372137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '12 Oct 2020'	(b) (4) Elena Acosta (b) (4) (b) (4)	12 Oct 2020 13:13:57

US3372137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Clinic (Clinic)'	(b) (4) Elena Acosta (b) (4) (b) (4)	12 Oct 2020 13:13:57

US3372137

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'VISIT3'	System	12 Oct 2020 13:13:57

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered empty.	System	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered empty.	System	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered empty.	System	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered empty.	System	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4)	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered empty.	System	06 Nov 2020 23:07:30

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18

US3372137

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18

US3372137

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	06 Nov 2020 23:07:33

US3372137

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	06 Nov 2020 23:07:33

US3372137

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	06 Nov 2020 23:07:40

US3372137

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '12 Oct 2020'	(b) (4) Peter Jacob (b) (4)	06 Nov 2020 23:07:40

US3372137

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered '09:43'	(b) (4) Peter Jacob (b) (4)	06 Nov 2020 23:07:40

US3372137

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered '12 Oct 2020 09:43'	System	06 Nov 2020 23:07:40

US3372137

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:20:46
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	06 Nov 2020 23:07:43

US3372137

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'I'	System	06 Nov 2020 23:07:43

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 64'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-10-14T11:35:38', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '400278d0-ec05-4ded-941f-2cc1c89f8716'	System	14 Oct 2020 15:36:19
User entered 'No (N)'	System	14 Oct 2020 15:36:19

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-10-14T11:35:44', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '400278d0-ec05-4ded-941f-2cc1c89f8716'	System	14 Oct 2020 15:36:19
User entered 'No (N)'	System	14 Oct 2020 15:36:19

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-10-14T11:36:17', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '400278d0-ec05-4ded-941f-2cc1c89f8716' User entered '14 Oct 2020 11:36:17'	System	14 Oct 2020 15:36:19
	System	14 Oct 2020 15:36:19

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 71'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-10-21T10:51:06', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f9ade825-90d1-4a16-b900-d3eadcf4602e' User entered 'No (N)'	System	21 Oct 2020 14:51:22
	System	21 Oct 2020 14:51:22

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-10-21T10:51:10', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f9ade825-90d1-4a16-b900-d3eadcf4602e' User entered 'No (N)'	System	21 Oct 2020 14:51:22
	System	21 Oct 2020 14:51:22

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-10-21T10:51:16', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f9ade825-90d1-4a16-b900-d3eadcf4602e' User entered '21 Oct 2020 10:51:16'	System	21 Oct 2020 14:51:22
	System	21 Oct 2020 14:51:22

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 78'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-10-28T06:41:30', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b86fafd4-232d-41fa-bf24-7de614128851'	System	28 Oct 2020 10:41:43
User entered 'No (N)'	System	28 Oct 2020 10:41:43

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-10-28T06:41:35', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b86fafd4-232d-41fa-bf24-7de614128851'	System	28 Oct 2020 10:41:43
User entered 'No (N)'	System	28 Oct 2020 10:41:43

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-10-28T06:41:40', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b86fafd4-232d-41fa-bf24-7de614128851' User entered '28 Oct 2020 06:41:40'	System	28 Oct 2020 10:41:43
	System	28 Oct 2020 10:41:43

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 92'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-11T03:16:07', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b3d529da-d59e-40c2-af96-93b6b17ae754' User entered 'No (N)'	System	11 Nov 2020 15:39:28
	System	11 Nov 2020 15:39:28

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-11T10:39:21', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b3d529da-d59e-40c2-af96-93b6b17ae754'	System	11 Nov 2020 15:39:28
User entered 'No (N)'	System	11 Nov 2020 15:39:28

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-11T10:39:25', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b3d529da-d59e-40c2-af96-93b6b17ae754' User entered '11 Nov 2020 10:39:25'	System	11 Nov 2020 15:39:28
	System	11 Nov 2020 15:39:28

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered 'Day 99'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-18T22:52:25', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f037d65d-2d5a-455e-b72f-fad0e2cba73f' User entered 'No (N)'	System	19 Nov 2020 03:52:47
	System	19 Nov 2020 03:52:47

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-18T22:52:38', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f037d65d-2d5a-455e-b72f-fad0e2cba73f' User entered 'No (N)'	System	19 Nov 2020 03:52:47
	System	19 Nov 2020 03:52:47

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-18T22:52:43', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f037d65d-2d5a-455e-b72f-fad0e2cba73f' User entered '18 Nov 2020 22:52:43'	System	19 Nov 2020 03:52:47
	System	19 Nov 2020 03:52:47

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 20:31:21

US3372137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:38:42
Data entry locked.	System	14 Aug 2020 20:31:21
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 20:31:21

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-25T11:23:17', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '47020a12-eee0-47c9-842c-fc23cef728cc' User entered 'No (N)'	System	25 Nov 2020 16:23:33
	System	25 Nov 2020 16:23:33

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-25T11:23:24', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '47020a12-eee0-47c9-842c-fc23cef728cc' User entered 'No (N)'	System	25 Nov 2020 16:23:33

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-25T11:23:27', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '47020a12-eee0-47c9-842c-fc23cef728cc' User entered '25 Nov 2020 11:23:27'	System	25 Nov 2020 16:23:33

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-29T03:04:08', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '17474925-544b-490e-a40f-e5759a8e89cf' User entered 'No (N)'	System	29 Nov 2020 08:04:22

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-29T03:04:15', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '17474925-544b-490e-a40f-e5759a8e89cf' User entered 'No (N)'	System	29 Nov 2020 08:04:22

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-11-29T03:04:20', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '17474925-544b-490e-a40f-e5759a8e89cf' User entered '29 Nov 2020 03:04:20'	System	29 Nov 2020 08:04:22
	System	29 Nov 2020 08:04:22

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-06T23:41:03', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '91bd387f-7ae9-4f31-8e8f-c4d298035286'	System	07 Dec 2020 04:41:30
User entered 'No (N)'	System	07 Dec 2020 04:41:30

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-06T23:41:15', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '91bd387f-7ae9-4f31-8e8f-c4d298035286'	System	07 Dec 2020 04:41:30
User entered 'No (N)'	System	07 Dec 2020 04:41:30

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-06T23:41:26', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '91bd387f-7ae9-4f31-8e8f-c4d298035286' User entered '06 Dec 2020 23:41:26'	System	07 Dec 2020 04:41:30
	System	07 Dec 2020 04:41:30

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-13T09:26:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '63396bb5-3423-43f7-a17e-956e600281bd' User entered 'No (N)'	System	13 Dec 2020 14:26:12
	System	13 Dec 2020 14:26:12

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-13T09:26:05', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '63396bb5-3423-43f7-a17e-956e600281bd' User entered 'No (N)'	System	13 Dec 2020 14:26:12

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-13T09:26:10', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '63396bb5-3423-43f7-a17e-956e600281bd' User entered '13 Dec 2020 09:26:10'	System	13 Dec 2020 14:26:12
	System	13 Dec 2020 14:26:12

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:05:55', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered 'Yes (Y)'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:05', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered 'No (N)'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

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)
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:40:37
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 19:35:27
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:13:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:12', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456'	System	20 Dec 2020 11:07:34
User entered 'Yes (Y)'	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '1'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '1'	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '1'	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '0'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Please 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:06:59', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456'	System	20 Dec 2020 11:07:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:07:06', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered 'Yes (Y)'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Please 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:07:12', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456'	System	20 Dec 2020 11:07:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-20T06:07:25', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '5743e3b0-c01f-4ba6-813e-98d06332e456' User entered '20 Dec 2020 06:07:25'	System	20 Dec 2020 11:07:34
	System	20 Dec 2020 11:07:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-28T08:59:03', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'e07e6c52-f5db-4faa-9b08-71f33a65fcba' User entered 'No (N)'	System	28 Dec 2020 13:59:18
	System	28 Dec 2020 13:59:18

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-28T08:59:10', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'e07e6c52-f5db-4faa-9b08-71f33a65fcba' User entered 'No (N)'	System	28 Dec 2020 13:59:18

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2020-12-28T08:59:15', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'e07e6c52-f5db-4faa-9b08-71f33a65fcba' User entered '28 Dec 2020 08:59:15'	System	28 Dec 2020 13:59:18
	System	28 Dec 2020 13:59:18

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-04T10:33:44', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f7070a40-994d-4a8e-86c1-1b11bbafce6b' User entered 'No (N)'	System	04 Jan 2021 15:33:58
	System	04 Jan 2021 15:33:58

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-04T10:33:49', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f7070a40-994d-4a8e-86c1-1b11bbafce6b' User entered 'No (N)'	System	04 Jan 2021 15:33:58

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-04T10:33:53', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'f7070a40-994d-4a8e-86c1-1b11bbafce6b' User entered '04 Jan 2021 10:33:53'	System	04 Jan 2021 15:33:58
	System	04 Jan 2021 15:33:58

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-12T12:22:02', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'e80f7b83-2d64-4549-a4f2-bb216e5c0afc' User entered 'No (N)'	System	12 Jan 2021 17:22:14
	System	12 Jan 2021 17:22:14

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-12T12:22:05', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'e80f7b83-2d64-4549-a4f2-bb216e5c0afc' User entered 'No (N)'	System	12 Jan 2021 17:22:14
	System	12 Jan 2021 17:22:14

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-12T12:22:09', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'e80f7b83-2d64-4549-a4f2-bb216e5c0afc' User entered '12 Jan 2021 12:22:09'	System	12 Jan 2021 17:22:14
	System	12 Jan 2021 17:22:14

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-20T18:38:48', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'bba0393a-0921-4a32-8b68-04a933884627' User entered 'No (N)'	System	20 Jan 2021 23:38:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-20T18:38:53', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'bba0393a-0921-4a32-8b68-04a933884627'	System	20 Jan 2021 23:38:59
User entered 'No (N)'	System	20 Jan 2021 23:38:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-20T18:38:56', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'bba0393a-0921-4a32-8b68-04a933884627' User entered '20 Jan 2021 18:38:56'	System	20 Jan 2021 23:38:59

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-24T22:35:29', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b12562cf-0167-45cd-8f66-18ecee28f5ba' User entered 'Yes (Y)'	System	25 Jan 2021 03:37:17
	System	25 Jan 2021 03:37:17

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-24T22:35:55', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b12562cf-0167-45cd-8f66-18ecee28f5ba' User entered 'No (N)'	System	25 Jan 2021 03:37:17

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-24T22:36:06', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b12562cf-0167-45cd-8f66-18ecee28f5ba' User entered 'No (N)'	System	25 Jan 2021 03:37:17
	System	25 Jan 2021 03:37:17

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-24T22:36:22', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b12562cf-0167-45cd-8f66-18ecee28f5ba'	System	25 Jan 2021 03:37:17
User entered 'Yes (Y)'	System	25 Jan 2021 03:37:17

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Please 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-24T22:36:59', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b12562cf-0167-45cd-8f66-18ecee28f5ba'	System	25 Jan 2021 03:37:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 03:37:17

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-24T22:37:07', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'b12562cf-0167-45cd-8f66-18ecee28f5ba' User entered '24 Jan 2021 22:37:07'	System	25 Jan 2021 03:37:17

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-31T07:17:37', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '7368644e-9023-48ce-bf9f-06341f6c0dfb' User entered 'No (N)'	System	31 Jan 2021 12:17:53
	System	31 Jan 2021 12:17:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-31T07:17:42', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '7368644e-9023-48ce-bf9f-06341f6c0dfb' User entered 'No (N)'	System	31 Jan 2021 12:17:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-01-31T07:17:48', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '7368644e-9023-48ce-bf9f-06341f6c0dfb' User entered '31 Jan 2021 07:17:48'	System	31 Jan 2021 12:17:53
	System	31 Jan 2021 12:17:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-09T10:17:09', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '2118c5a0-bff9-456d-a8cc-929a4798294d' User entered 'No (N)'	System	09 Feb 2021 15:29:09
	System	09 Feb 2021 15:29:09

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-09T10:17:15', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '2118c5a0-bff9-456d-a8cc-929a4798294d' User entered 'No (N)'	System	09 Feb 2021 15:29:09

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-09T10:17:20', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '2118c5a0-bff9-456d-a8cc-929a4798294d' User entered '09 Feb 2021 10:17:20'	System	09 Feb 2021 15:29:09
	System	09 Feb 2021 15:29:09

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-15T10:23:39', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6888ed89-ac6d-4519-aa39-3d55e1a8b17c' User entered 'No (N)'	System	15 Feb 2021 15:24:15
	System	15 Feb 2021 15:24:15

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-15T10:23:53', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6888ed89-ac6d-4519-aa39-3d55e1a8b17c' User entered 'No (N)'	System	15 Feb 2021 15:24:15
	System	15 Feb 2021 15:24:15

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-15T10:24:10', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '6888ed89-ac6d-4519-aa39-3d55e1a8b17c' User entered '15 Feb 2021 10:24:10'	System	15 Feb 2021 15:24:15
	System	15 Feb 2021 15:24:15

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-23T10:27:18', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '0e4b6593-7616-46c7-ad43-2440590ddf19' User entered 'Yes (Y)'	System	23 Feb 2021 15:28:05
	System	23 Feb 2021 15:28:05

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-23T10:27:22', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '0e4b6593-7616-46c7-ad43-2440590ddf19' User entered 'No (N)'	System	23 Feb 2021 15:28:05
	System	23 Feb 2021 15:28:05

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-23T10:27:27', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '0e4b6593-7616-46c7-ad43-2440590ddf19' User entered 'No (N)'	System	23 Feb 2021 15:28:05
	System	23 Feb 2021 15:28:05

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-23T10:27:35', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '0e4b6593-7616-46c7-ad43-2440590ddf19' User entered 'Yes (Y)'	System	23 Feb 2021 15:28:05
	System	23 Feb 2021 15:28:05

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Please 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-23T10:27:40', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '0e4b6593-7616-46c7-ad43-2440590ddf19'	System	23 Feb 2021 15:28:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Feb 2021 15:28:05

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-23T10:27:45', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '0e4b6593-7616-46c7-ad43-2440590ddf19' User entered '23 Feb 2021 10:27:45'	System	23 Feb 2021 15:28:05
	System	23 Feb 2021 15:28:05

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-28T01:19:09-05:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '9b3e35a8-5876-40de-98e2-728854bb69b6'	System	28 Feb 2021 06:19:19
User entered 'No (N)'	System	28 Feb 2021 06:19:19

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-28T01:19:12-05:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '9b3e35a8-5876-40de-98e2-728854bb69b6'	System	28 Feb 2021 06:19:19
User entered 'No (N)'	System	28 Feb 2021 06:19:19

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-28T01:19:16-05:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '9b3e35a8-5876-40de-98e2-728854bb69b6'	System	28 Feb 2021 06:19:19
User entered '28 Feb 2021 06:19:16'	System	28 Feb 2021 06:19:19

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-03-09T05:56:13-05:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '0c6988f1-27a7-477a-8a0b-bf48f52ca865'	System	09 Mar 2021 10:56:34
User entered 'No (N)'	System	09 Mar 2021 10:56:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-03-09T05:56:24-05:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '0c6988f1-27a7-477a-8a0b-bf48f52ca865'	System	09 Mar 2021 10:56:34
User entered 'No (N)'	System	09 Mar 2021 10:56:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-03-09T05:56:31-05:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '0c6988f1-27a7-477a-8a0b-bf48f52ca865' User entered '09 Mar 2021 05:56:31'	System	09 Mar 2021 10:56:34
	System	09 Mar 2021 10:56:34

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-03-22T17:06:52-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '33b392ba-6b20-4cd3-8b49-93128d6c12a5'	System	22 Mar 2021 21:07:27
User entered 'No (N)'	System	22 Mar 2021 21:07:27

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-03-22T17:07:07-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '33b392ba-6b20-4cd3-8b49-93128d6c12a5'	System	22 Mar 2021 21:07:27
User entered 'No (N)'	System	22 Mar 2021 21:07:27

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-03-22T17:07:22-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '33b392ba-6b20-4cd3-8b49-93128d6c12a5'	System	22 Mar 2021 21:07:27
User entered '22 Mar 2021 17:07:22'	System	22 Mar 2021 21:07:27

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-03-30T14:28:13-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '97eb53f6-aef2-4d76-a137-f688a3c70cae' User entered 'No (N)'	System	02 Apr 2021 00:00:49

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-03-30T14:28:19-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '97eb53f6-aef2-4d76-a137-f688a3c70cae' User entered 'No (N)'	System	02 Apr 2021 00:00:49

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-03-30T14:28:24-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '97eb53f6-aef2-4d76-a137-f688a3c70cae' User entered '30 Mar 2021 14:28:24'	System	02 Apr 2021 00:00:49
	System	02 Apr 2021 00:00:49

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-08T11:01:20-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a33b3200-f16c-436f-9ee9-9d10b3857557'	System	08 Apr 2021 15:01:40
User entered 'No (N)'	System	08 Apr 2021 15:01:40

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-08T11:01:27-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a33b3200-f16c-436f-9ee9-9d10b3857557'	System	08 Apr 2021 15:01:40
User entered 'No (N)'	System	08 Apr 2021 15:01:40

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-08T11:01:31-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'a33b3200-f16c-436f-9ee9-9d10b3857557'	System	08 Apr 2021 15:01:40
User entered '08 Apr 2021 11:01:31'	System	08 Apr 2021 15:01:40

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-13T12:42:19-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '56da8035-f98b-45c8-b6ca-962808ccb679' User entered 'No (N)'	System	17 Apr 2021 17:43:10
	System	17 Apr 2021 17:43:10

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-13T12:42:31-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '56da8035-f98b-45c8-b6ca-962808ccb679' User entered 'No (N)'	System	17 Apr 2021 17:43:10
	System	17 Apr 2021 17:43:10

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-13T12:42:36-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '56da8035-f98b-45c8-b6ca-962808ccb679'	System	17 Apr 2021 17:43:10
User entered '13 Apr 2021 12:42:36'	System	17 Apr 2021 17:43:10

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-18T20:27:59-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '8b62f034-8c5a-4d62-826e-3a7275af890e'	System	19 Apr 2021 00:28:10
User entered 'No (N)'	System	19 Apr 2021 00:28:10

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-18T20:28:03-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '8b62f034-8c5a-4d62-826e-3a7275af890e'	System	19 Apr 2021 00:28:10
User entered 'No (N)'	System	19 Apr 2021 00:28:10

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-18T20:28:06-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '8b62f034-8c5a-4d62-826e-3a7275af890e'	System	19 Apr 2021 00:28:10
User entered '18 Apr 2021 20:28:06'	System	19 Apr 2021 00:28:10

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-26T22:30:57-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '78f05991-9830-4045-a101-983b6469f785'	System	27 Apr 2021 02:31:23
User entered 'No (N)'	System	27 Apr 2021 02:31:23

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-26T22:31:04-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '78f05991-9830-4045-a101-983b6469f785'	System	27 Apr 2021 02:31:23
User entered 'No (N)'	System	27 Apr 2021 02:31:23

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-04-26T22:31:21-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '78f05991-9830-4045-a101-983b6469f785' User entered '26 Apr 2021 22:31:21'	System	27 Apr 2021 02:31:23
	System	27 Apr 2021 02:31:23

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-05-02T08:53:42-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'e367126e-7a25-4247-9e3f-38366631f188'	System	02 May 2021 12:53:57
User entered 'No (N)'	System	02 May 2021 12:53:57

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

Have you been exposed to someone with 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 (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-05-02T08:53:49-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'e367126e-7a25-4247-9e3f-38366631f188' User entered 'No (N)'	System	02 May 2021 12:53:57

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-05-02T08:53:54-04:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: 'e367126e-7a25-4247-9e3f-38366631f188'	System	02 May 2021 12:53:57
User entered '02 May 2021 08:53:54'	System	02 May 2021 12:53:57

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:48:53

US3372137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:13:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:48:53
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:48:53

US3372137

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:13:43

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)	26 Apr 2021 06:47:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-28T01:19:22-05:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '98e8b0a1-af31-4525-a0e7-7c797b981102'	System	28 Feb 2021 06:19:46
User entered 'Yes (Y)'	System	28 Feb 2021 06:19:46

US3372137

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:13:43

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:47:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-28T01:19:28-05:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '98e8b0a1-af31-4525-a0e7-7c797b981102'	System	28 Feb 2021 06:19:46
User entered 'No (N)'	System	28 Feb 2021 06:19:46

US3372137

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:13:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:47:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A84EA1AD-2DB9-4AFB-B246-05E46F94C420)', Time: '2021-02-28T01:19:36-05:00', User OID: 'PatientReportedOutcome (US3372137)', ODM File OID: '98e8b0a1-af31-4525-a0e7-7c797b981102'	System	28 Feb 2021 06:19:46
User entered '28 Feb 2021 06:19:36'	System	28 Feb 2021 06:19:46

US3372137

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	10 Nov 2020 15:22:34
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '10 Nov 2020'	(b) (4)	10 Nov 2020 15:22:34
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	10 Nov 2020 15:22:34
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4)	10 Nov 2020 15:22:34
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	10 Nov 2020 15:22:46
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:07:18
User entered 'I'	System	10 Nov 2020 15:22:46

US3372137

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 21DEC2020, however, this sample is missing in EDC. Please enter the 21DEC2020 Swab sample in the Covid-19 Assessment folder, as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:28:27
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 21DEC2020, however, this sample is missing in EDC. Please enter the 21DEC2020 Swab sample in the Covid-19 Assessment folder, as appropriate.'	(b) (4), (b) (6)	05 Jan 2021 19:05:33
answered with 'data updated' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 21DEC2020, however, this sample is missing in EDC. Please enter the 21DEC2020 Swab sample in the Covid-19 Assessment folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 22:51:50
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	15 Dec 2020 17:18:36
	(b) (4)	

US3372137

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '15 Dec 2020'	(b) (4)	15 Dec 2020 17:18:36
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	15 Dec 2020 17:18:36
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4)	
	Danielle Theodore (b) (4)	15 Dec 2020 17:18:36
	(b) (4)	

US3372137

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	15 Dec 2020 17:18:42
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User entered 'I'	System	15 Dec 2020 17:18:42

US3372137

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 20:01:57
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '13 Jan 2021'	(b) (4)	13 Jan 2021 20:01:57
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	13 Jan 2021 20:01:57
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4)	
	Danielle Theodore (b) (4)	13 Jan 2021 20:01:57
	(b) (4)	

US3372137

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 20:02:04
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:59:41
User entered 'I'	System	13 Jan 2021 20:02:04

US3372137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:50:19
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	17 Mar 2021 16:28:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Danielle Theodore (b) (4)	17 Mar 2021 16:28:49
	(b) (4)	
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	11 Mar 2021 17:52:21
User entered 'No (N)'	Danielle Theodore (b) (4)	11 Mar 2021 17:52:21
	(b) (4)	

US3372137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:50:19
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	17 Mar 2021 16:29:50
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	17 Mar 2021 16:29:50
User entered '9 Feb 2021' reason for change: Data Entry Error	Danielle Theodore (b) (4)	17 Mar 2021 16:29:50
	(b) (4)	
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Mar 2021 16:28:49
User entered '8 Feb 2021' reason for change: Data Entry Error	Danielle Theodore (b) (4)	17 Mar 2021 16:28:49
	(b) (4)	
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 11:54:16
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'that was the last interaction had with subject. he is no longer in the study' (Site from System).	Danielle Theodore (b) (4)	11 Mar 2021 17:53:35
	(b) (4)	

US3372137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Mar 2021 17:53:05
User entered '18 Jan 2021' reason for change: Data Entry Error	Danielle Theodore (b) (4) (b) (4) (b) (4)	11 Mar 2021 17:53:05
User entered empty.	Danielle Theodore (b) (4) (b) (4) (b) (4)	11 Mar 2021 17:52:21

US3372137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:50:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Danielle Theodore (b) (4)	17 Mar 2021 16:28:49
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Danielle Theodore (b) (4)	11 Mar 2021 17:52:21
	(b) (4)	

US3372137

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:50:19
User entered empty; reason for change Data Entry Error	(b) (4) Danielle Theodore (b) (4)	17 Mar 2021 16:28:49
	(b) (4)	
User entered 'Subject no longer in study'	Danielle Theodore (b) (4)	11 Mar 2021 17:52:21
	(b) (4)	

US3372137

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:50:19
Signature has been broken.	(b) (4)	
	Danielle Theodore (b) (4)	17 Mar 2021 16:30:02
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Danielle Theodore (b) (4)	17 Mar 2021 16:30:02
	(b) (4)	
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:33:16
User entered 'No (N)'	(b) (4)	
	Danielle Theodore (b) (4)	11 Mar 2021 17:53:42
	(b) (4)	

US3372137

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:01:09
User entered 'I'	System	17 Mar 2021 16:30:02
User entered empty.	System	11 Mar 2021 17:53:42

US3372137

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:34

US3372137

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:34

US3372137

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[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 12:31:41
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:04:34

US3372137

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'VISIT4'	System	23 Mar 2021 21:04:34

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User closed query 'Per CDM re-query: Per sponsor review Visit 4 and OL-D57 took place exactly the same time. Please consider updating Visit 4 Vital Signs form. Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 06:43:26
Query 'Per CDM re-query: Per sponsor review Visit 4 and OL-D57 took place exactly the same time. Please consider updating Visit 4 Vital Signs form. Thank you!' answered with 'Data correct as is.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:00:21
User opened query 'Per CDM re-query: Per sponsor review Visit 4 and OL-D57 took place exactly the same time. Please consider updating Visit 4 Vital Signs form. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 10:49:54
User closed query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 10:49:54
Query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' answered with 'data correct as is' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:03:47
User opened query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 03:08:04
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:17:28
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:17:28
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered empty.	System	02 Apr 2021 20:01:05

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 12:31:41

US3372137

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41

US3372137

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:16

US3372137

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:16

US3372137

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:05:44

US3372137

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:05:44

US3372137

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '15:02'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:05:44

US3372137

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered '23 Mar 2021 15:02'	System	23 Mar 2021 21:05:44

US3372137

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:05:50

US3372137

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:31:41
User entered 'I'	System	23 Mar 2021 21:05:50

US3372137

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:02
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	13 Apr 2021 16:41:09
	(b) (4)	

US3372137

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:02
	(b) (4)	
User entered '13 Apr 2021'	Danielle Theodore (b) (4)	13 Apr 2021 16:41:09
	(b) (4)	

US3372137

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Danielle Theodore (b) (4)	13 Apr 2021 16:41:09
	(b) (4)	

US3372137

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:02
	(b) (4)	
User entered empty.	Danielle Theodore (b) (4)	13 Apr 2021 16:41:09
	(b) (4)	

US3372137

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:02
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	13 Apr 2021 16:41:15
	(b) (4)	

US3372137

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 16:41:15

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:13:43

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:03
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '21 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:19:15

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:13:43

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:03
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14:00'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:19:15

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:13:43

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:03
User entered '21 Dec 2020 14:00'	System	30 Dec 2020 20:19:15

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:13:43

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:03
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:19:15

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:13:43

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:03
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:19:15

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Day 10 (Day 10)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '21 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '97'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User entered '%'	System	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '98.2' F	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Mild (Mild)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Mild (Mild)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Mild (Mild)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:13:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:22:17

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Day 11 (Day 11)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '22 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '98'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User entered '%'	System	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '97.6' F	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Mild (Mild)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:13:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:23:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Day 12 (Day 12)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '23 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '98'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User entered '%'	System	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '97.4' F	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Mild (Mild)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:13:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:25:07

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Day 13 (Day 13)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '24 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '98'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User entered '%'	System	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '97.8' F	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Mild (Mild)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:13:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:26:27

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Day 14 (Day 14)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '25 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '98'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User entered '%'	System	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '97.8' F	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Mild (Mild)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:13:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:27:29

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Day 15 (Day 15)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '26 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '98'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User entered '%'	System	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '97.8' F	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Mild (Mild)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:13:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:28:37

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Day 16 (Day 16)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '27 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '97'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User entered '%'	System	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '97.6' F	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Mild (Mild)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:29:47

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:13:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4)	30 Dec 2020 20:29:47
	Mary Sergalis (b) (4)	

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Day 17 (Day 17)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '28 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '97'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User entered '%'	System	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '97.6' F	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:13:43

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:08
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'None (None)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:31:42

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:13:43

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '21 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:34:08

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:13:43

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:34:08

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:13:43

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:34:08

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:13:43

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '21 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:34:08

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:13:43

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:34:08

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:13:43

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:34:08

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:13:43

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:34:08

US3372137

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:13:43

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:34:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:34:08

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Folder: Covid-19 Assessment 21 Dec 2020

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:13
User entered '0'	System	30 Dec 2020 20:34:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:13:43

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:19
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:34:14

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:13:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	05 Jan 2021 17:43:33

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:13:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	26 Mar 2021 21:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 20:09:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 17:43:33

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:13:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	26 Mar 2021 21:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 20:09:07
User entered '23 Dec 2020'	(b) (4), (b) (6)	05 Jan 2021 17:43:33

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:13:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	05 Jan 2021 17:44:00

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:13:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	26 Mar 2021 21:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 20:08:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 17:44:00

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:13:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	26 Mar 2021 21:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 20:08:49
User entered '25 Dec 2020'	(b) (4), (b) (6)	05 Jan 2021 17:44:00

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:13:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	05 Jan 2021 17:44:17

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:13:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	26 Mar 2021 21:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 20:12:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 17:44:17

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:13:43

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29DEC2020 is reported under Illness visit 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)	31 Mar 2021 04:06:31
User signature succeeded.	Mira Baron (b) (4)	26 Mar 2021 21:03:07
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29DEC2020 is reported under Illness visit 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 'Subject received a negative COVID result on Conalascent day 8 and was returned to their regular study schedule.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:00:36
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:12:41
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29DEC2020 is reported under Illness visit 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)	08 Jan 2021 04:58:35
User entered '27 Dec 2020'	(b) (4), (b) (6)	05 Jan 2021 17:44:17

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:13:43

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Please confirm is saliva sample was collected for this subject, if yes kindly update day 9 details.Thanks' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:53:02
Query 'Per GCL Lab Recon: Saliva: Please confirm is saliva sample was collected for this subject, if yes kindly update day 9 details.Thanks' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 17:01:39
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	22 Apr 2021 17:01:19
User opened query 'Per GCL Lab Recon: Saliva: Please confirm is saliva sample was collected for this subject, if yes kindly update day 9 details.Thanks' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 03:55:07
Amendment Manager: User entered 'Day 9 (Day 9)'	System	27 Mar 2021 07:40:06

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:13:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 20:21:35
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:01:19

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:13:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 20:21:35
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:01:19

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:13:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	22 Apr 2021 17:02:44
Amendment Manager: User entered 'Day 14 (Day 14)'	System	27 Mar 2021 07:40:06

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:13:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 20:21:35
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:02:44

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:13:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 20:21:35
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:02:44

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:13:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	22 Apr 2021 17:02:44
Amendment Manager: User entered 'Day 21 (Day 21)'	System	27 Mar 2021 07:40:06

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:13:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 20:21:35
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:02:44

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:13:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 20:21:35
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:02:44

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:13:43

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	22 Apr 2021 17:02:44
Amendment Manager: User entered 'Day 28 (Day 28)'	System	27 Mar 2021 07:40:06

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:13:43

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 20:21:35
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:02:44

US3372137

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:13:43

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 20:21:35
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:02:44

US3372137

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:25:03
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	30 Dec 2020 20:36:11
	Mary Sergalis (b) (4)	

US3372137

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:25:04
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '21 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:36:11

US3372137

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:25:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Clinic (Clinic)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:36:11

US3372137

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
User entered 'SICKD1'	System	30 Dec 2020 20:36:11

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:25:25
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	30 Dec 2020 20:39:09
	Mary Sergalis (b) (4)	

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:25:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '21 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:39:09

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:25:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '14:05'	(b) (4)	30 Dec 2020 20:39:09
	Mary Sergalis (b) (4)	

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
User entered '21 Dec 2020 14:05'	System	30 Dec 2020 20:39:09

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '70' in	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:39:09
DataPoint set to visible.	System	30 Dec 2020 20:36:11

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:25:58
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '176.3' lb	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:39:09
DataPoint set to visible.	System	30 Dec 2020 20:36:11

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:25:35
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '98.2' F	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:39:09

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:26:15
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Other (Other)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:39:09

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:26:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'infrared forehead'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:39:09

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:26:22
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '87'	(b) (4)	30 Dec 2020 20:39:09
	Mary Sergalis (b) (4)	

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
User entered 'bpm'	System	30 Dec 2020 20:39:09

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:26:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '20'	(b) (4)	30 Dec 2020 20:39:09
	Mary Sergalis (b) (4)	

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
User entered 'breaths/min'	System	30 Dec 2020 20:39:09

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:26:33
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '128'	(b) (4)	30 Dec 2020 20:39:09
	Mary Sergalis (b) (4)	

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
User entered 'mmHg'	System	30 Dec 2020 20:39:09

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:26:37
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '62'	(b) (4)	30 Dec 2020 20:39:09
	Mary Sergalis (b) (4)	

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
User entered 'mmHg'	System	30 Dec 2020 20:39:09

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43

US3372137

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43

US3372137

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:31:46
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	30 Dec 2020 20:39:29
	Mary Sergalis (b) (4)	

US3372137

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:31:48
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '21 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:39:29

US3372137

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:13:43

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:42:00
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:39:47

US3372137

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:13:43

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:48:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:42:03
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '21 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	30 Dec 2020 20:39:47

US3372137

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

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'Yes (Y)'	(b) (4)	02 Feb 2021 15:27:45
	(b) (4)	

US3372137

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

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 10:20:50
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 10:20:46
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26Jan2021 is reported under OL-1 visit 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 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	20 Feb 2021 23:03:39
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	20 Feb 2021 23:03:35

US3372137

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

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26Jan2021 is reported under OL-1 visit 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)	05 Feb 2021 13:47:47
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate in Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 10:11:47
User entered '26 Jan 2021'	Danielle Theodore (b) (4)	02 Feb 2021 15:27:45
	(b) (4)	

US3372137

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

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'Clinic (Clinic)'	(b) (4)	
	Danielle Theodore (b) (4)	02 Feb 2021 15:27:45
	(b) (4)	

US3372137

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

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 15:27:45

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '26 Jan 2021'	(b) (4)	02 Feb 2021 15:28:08
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:33:16
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:42:13

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	02 Feb 2021 15:28:08
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:33:16
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:42:13

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '26 Jan 2021'	(b) (4)	02 Feb 2021 15:28:08
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Placebo (Placebo)'	(b) (4) Danielle Theodore (b) (4)	02 Feb 2021 15:28:08
	(b) (4)	

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Placebo (Placebo)'	(b) (4)	02 Feb 2021 15:28:08
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Placebo (Placebo)'	(b) (4)	02 Feb 2021 15:28:08
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	02 Feb 2021 15:28:08
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '1'	System	02 Feb 2021 15:28:08

US3372137

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

Form: Unblinding

Generated On: 09 Jun 2021 17:13:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'I'	System	02 Feb 2021 15:28:08

US3372137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '177.8' cm	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '83.1' kg	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '26.28679'	System	20 Feb 2021 21:29:52
DataPoint set to visible.	System	02 Feb 2021 15:28:08

US3372137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '177.8' cm	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '83.1' kg	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '26.28679'	System	20 Feb 2021 21:29:52
DataPoint set to visible.	System	02 Feb 2021 15:28:08

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	20 Feb 2021 22:20:45
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	20 Feb 2021 21:32:44
User entered '13:30'	(b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '26 Jan 2021 13:30'	System	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'infrared forehead'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '76'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'bpm'	System	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '17'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'breaths/min'	System	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '121'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mmHg'	System	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '67'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mmHg'	System	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '177.8' cm	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '83.1' kg	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:13:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '26.28679'	System	20 Feb 2021 21:29:52
DataPoint set to visible.	System	02 Feb 2021 15:28:08

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '15:27'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '26 Jan 2021 15:27'	System	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'infrared forehead'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '71'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'bpm'	System	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '18'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'breaths/min'	System	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '134'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mmHg'	System	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '75'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:29:52

US3372137

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mmHg'	System	20 Feb 2021 21:29:52

US3372137

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:30:07

US3372137

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:30:07

US3372137

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

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:32:44

US3372137

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

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:32:44

US3372137

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

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

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)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:32:44

US3372137

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

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mRNA-1273'	System	20 Feb 2021 21:32:44
DataPoint set to visible.	System	02 Feb 2021 15:28:08

US3372137

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

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:32:44

US3372137

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

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '14:56' reason for change: Data Entry Error	(b) (4)	20 Feb 2021 22:20:45
User entered '13:10'	Peter Jacob (b) (4)	20 Feb 2021 21:32:44
	(b) (4), (b) (6)	

US3372137

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

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '26 Jan 2021 14:56'	System	20 Feb 2021 22:20:45
User entered '26 Jan 2021 13:10'	System	20 Feb 2021 21:32:44

US3372137

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

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:32:44

US3372137

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

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'ONCE'	System	20 Feb 2021 21:32:44

US3372137

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

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'INTRAMUSCULAR'	System	20 Feb 2021 21:32:44

US3372137

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:33:04

US3372137

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:33:04

US3372137

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '13:07'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:33:04

US3372137

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '26 Jan 2021 13:07'	System	20 Feb 2021 21:33:04

US3372137

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:33:20

US3372137

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:33:20

US3372137

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:51:09
User entered '13:05'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 21:33:20

US3372137

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:13:43

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '26 Jan 2021 13:05'	System	20 Feb 2021 21:33:20

US3372137

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

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	02 Feb 2021 15:28:14
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

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

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'I'	System	02 Feb 2021 15:28:14

US3372137

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	02 Feb 2021 15:28:46
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '2 Feb 2021'	(b) (4)	02 Feb 2021 15:28:46
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Danielle Theodore (b) (4)	02 Feb 2021 15:28:46
	(b) (4)	

US3372137

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4)	
	Danielle Theodore (b) (4)	02 Feb 2021 15:28:46
	(b) (4)	

US3372137

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4)	02 Feb 2021 15:28:52
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'I'	System	02 Feb 2021 15:28:52

US3372137

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'I'	System	02 Feb 2021 15:28:52
DataPoint set to visible.	System	02 Feb 2021 15:28:52

US3372137

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:10:25

US3372137

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:10:25

US3372137

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:10:25

US3372137

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'OLD29'	System	25 Feb 2021 16:10:25

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '09:19'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '24 Feb 2021 09:19'	System	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '73'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'bpm'	System	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '18'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'breaths/min'	System	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '136'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mmHg'	System	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '65'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mmHg'	System	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '11:08'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '24 Feb 2021 11:08'	System	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '67'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'bpm'	System	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '18'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'breaths/min'	System	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '130'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mmHg'	System	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '75'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:13:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mmHg'	System	25 Feb 2021 16:12:04

US3372137

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:10

US3372137

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:10

US3372137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:37

US3372137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:37

US3372137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

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)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:37

US3372137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mRNA-1273'	System	25 Feb 2021 16:12:37
DataPoint set to visible.	System	02 Feb 2021 15:28:52

US3372137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:37

US3372137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered '10:33'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:37

US3372137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '24 Feb 2021 10:33'	System	25 Feb 2021 16:12:37

US3372137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:37

US3372137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'ONCE'	System	25 Feb 2021 16:12:37

US3372137

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:13:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 16:12:37

US3372137

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	25 Feb 2021 23:12:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:12:49

US3372137

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'I'	System	25 Feb 2021 16:12:49

US3372137

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:33:16
User entered 'Yes (Y)'	(b) (4)	
	Danielle Theodore (b) (4)	03 Mar 2021 18:21:25
	(b) (4)	

US3372137

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:33:16
User entered '3 Mar 2021'	(b) (4)	
	Danielle Theodore (b) (4)	03 Mar 2021 18:21:25
	(b) (4)	

US3372137

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:33:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Danielle Theodore (b) (4)	03 Mar 2021 18:21:25
	(b) (4)	

US3372137

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:13:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:33:16
User entered empty.	(b) (4)	
	Danielle Theodore (b) (4)	03 Mar 2021 18:21:25
	(b) (4)	

US3372137

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:33:16
User entered 'Yes (Y)'	(b) (4)	03 Mar 2021 18:21:31
	Danielle Theodore (b) (4)	
	(b) (4)	

US3372137

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:13:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'I'	System	03 Mar 2021 18:21:31

US3372137

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:36

US3372137

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:36

US3372137

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:36

US3372137

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:13:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'OLD57'	System	23 Mar 2021 21:07:36

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '14:50'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '23 Mar 2021 14:50'	System	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'forehead'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '71'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'bpm'	System	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'breaths/min'	System	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '119'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mmHg'	System	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '69'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered 'mmHg'	System	23 Mar 2021 21:08:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27

US3372137

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:13:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27

US3372137

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:47

US3372137

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:13:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:47

US3372137

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:03

US3372137

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:03

US3372137

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '15:02'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:09:03

US3372137

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:13:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:29:27
User entered '23 Mar 2021 15:02'	System	23 Mar 2021 21:09:03

US3372137

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:13:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:11
User closed query '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)	26 Mar 2021 05:08:04
Query '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 'Subject has no AEs to report.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:11:17
User opened query '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)	25 Mar 2021 08:32:45
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	26 Jan 2021 19:34:56
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 18:49:38

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 14:47:25
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:12
User entered		
'USA-US056-2021-mRNA-1273-P301000004'	System	27 Jan 2021 18:49:09
User entered 'New'	(b) (4), (b) (6)	27 Jan 2021 18:49:09

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:47:29
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 21:38:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 21:38:59
Data point term sent to Coder	System	26 Jan 2021 21:38:34
User entered 'Dizziness'	Mary Sergalis (b) (4) 	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:47:27
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:47:31
User entered 'No (N)'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:47:33
User entered 'No (N)'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:47:37
User entered '19 Jan 2021'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 14:47:42
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Jan 2021 21:39:34
User entered empty; reason for change Data Entry Error	Mary Sergalis (b) (4)	26 Jan 2021 21:39:34
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Jan 2021 21:38:33
User entered '14:00'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 21:39:34
User entered '19 Jan 2021 14:00'	System	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:47:40
User entered 'No (N)'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:47:39
User entered '22 Jan 2021'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 14:47:46
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	26 Jan 2021 21:39:34
User entered empty; reason for change Data Entry Error	Mary Sergalis (b) (4)	26 Jan 2021 21:39:34
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	26 Jan 2021 21:38:33
User entered '15:00'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 21:39:34
User entered '22 Jan 2021 15:00'	System	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:48:16
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:47:48
User entered 'Yes (Y)'	Mary Sergalis (b) (4) 	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:48:22
User entered '0'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:48:24
User entered '0'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:48:21
User entered 'I'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:48:26
User entered '19 Jan 2021'	Mary Sergalis (b) (4) 	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:48:28
User entered '22 Jan 2021'	Mary Sergalis (b) (4) 	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 15:34:30
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 15:34:28
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
User entered empty.	(b) (4)	26 Jan 2021 21:38:33
	Mary Sergalis (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:48:34
User entered '0'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:48:35
User entered '0'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:48:37
User entered '0'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please be aware that according to a CRF Completion Guideline, "Not applicable" can be selected only if AE started before the first dose of IP. Please consider selecting related or not related. Thank you!' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	25 Feb 2021 05:58:14
DataPoint Verified.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
Query 'Per CDM: Please be aware that according to a CRF Completion Guideline, "Not applicable" can be selected only if AE started before the first dose of IP. Please consider selecting related or not related. Thank you!' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 19:08:14
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 15:55:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 15:54:56
User opened query 'Per CDM: Please be aware that according to a CRF Completion Guideline, "Not applicable" can be selected only if AE started before the first dose of IP. Please consider selecting related or not related. Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 14:48:54
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:43:24
User signature succeeded.	Mira Baron (b) (4)	07 Apr 2021 18:53:11
User closed query 'PV Query: Relatedness to study procedure was reported as not applicable. As subject received both scheduled doses, please update relatedness to not related or related to study procedure.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:37:48
Query 'PV Query: Relatedness to study procedure was reported as not applicable. As subject received both scheduled doses, please update relatedness to not related or related to study procedure.' answered with 'Data updated.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 19:37:30
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 19:37:07
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 19:37:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 19:37:07
User opened query 'PV Query: Relatedness to study procedure was reported as not applicable. As subject received both scheduled doses, please update relatedness to not related or related to study procedure.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:08:02
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:48:56
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the subject had already received both the doses of study drug prior to the event onset, please consider updating the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 01:24:18
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:08:25
Query 'PV Query: As the subject had already received both the doses of study drug prior to the event onset, please consider updating the action taken from none to not applicable.' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:55:35
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 15:54:56
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 15:54:56
User opened query 'PV Query: As the subject had already received both the doses of study drug prior to the event onset, please consider updating the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 17:42:14
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 14:48:58
User entered 'None (NONE)'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

None

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:45:52
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		18 Mar 2021 15:25:16
DataPoint Un-verified.	Mary Sergalis (b) (4)	18 Mar 2021 15:25:16
Signature has been broken.	Mary Sergalis (b) (4)	18 Mar 2021 15:25:16
User entered '0' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Mar 2021 15:25:16
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	18 Mar 2021 15:25:00
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 05:45:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 15:34:39
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with ' According to the Source no treatment was given for this AE' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:56:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). User entered 'I'	(b) (4), (b) (6) Mary Sergalis (b) (4) 	16 Feb 2021 06:24:56 26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 15:35:00
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
User entered '0'	(b) (4) Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
User closed query 'Please verify, medical records note tests were performed.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:45:57
	(b) (4), (b) (6)	18 Mar 2021 15:45:54
Signature has been broken.	Mary Sergalis (b) (4)	18 Mar 2021 15:25:00
User entered '1' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Mar 2021 15:25:00
Query 'Please verify, medical records note tests were performed.' answered with 'Subject did not have any Con Proc for this AE.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:52:23
User opened query 'Please verify, medical records note tests were performed.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 15:36:10
User closed query 'Please verify if tests done in the hospital should be entered.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 15:36:10
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
Query 'Please verify if tests done in the hospital should be entered.' answered with 'No Concomitant procedures taken for this AE' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:57:09
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 21:49:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:49:13
User opened query 'Please verify if tests done in the hospital should be entered.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 21:48:52
User entered '0'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 15:33:52
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
User entered empty.	(b) (4) Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Narrative](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:24:27
	(b) (4), (b) (6)	25 Feb 2021 15:34:16
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:50:27
	(b) (4)	
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 'No other data regarding this AE is available' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:57:41
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).	(b) (4), (b) (6)	04 Feb 2021 17:41:41
User entered 'Subject US 3372137 presented an episode of dizziness for which she was hospitalized on 19 January 2021. The subject was discharged on 22 Jan 2021. Subject was prescribed Meclizine PRN, but she confirmed she did not take the medication. At the moment of the site's visit the subject did not present any symptoms and she stated feeling good.'	Mary Sergalis (b) (4)	26 Jan 2021 21:38:33

US3372137

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Jan 2021 21:38:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #3 and 6 (SINUS CONGESTION and UPPER RESPIRATORY INFECTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:40:05
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #3 and 6 (SINUS CONGESTION and UPPER RESPIRATORY INFECTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' answered with 'These AEs were not related to a Positive COVID result therefore are individual AEs.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 19:39:29
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #3 and 6 (SINUS CONGESTION and UPPER RESPIRATORY INFECTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:45:21
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	23 Mar 2021 19:27:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 19:27:40
Data point term sent to Coder	System	23 Mar 2021 19:26:39
User entered 'Cough'	(b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User entered empty.	System	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User entered empty.	System	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User entered '0'	System	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30
User entered '0'	System	23 Mar 2021 19:26:14

US3372137

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:30

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:32:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:32:40
Data point term sent to Coder	System	23 Mar 2021 19:31:59
User entered 'Sinus Congestion'	(b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User entered empty.	System	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '19 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User entered empty.	System	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User entered '0'	System	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43
User entered '0'	System	23 Mar 2021 19:31:28

US3372137

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:43

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:33:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:33:41
Data point term sent to Coder	System	23 Mar 2021 19:33:00
User entered 'Headache'	(b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User entered empty.	System	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User entered empty.	System	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User entered '0'	System	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User entered '0'	System	23 Mar 2021 19:32:14

US3372137

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:40:15
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' answered with 'This was not caused by an underlying medical condition as the Subject does not have any related MH conditions.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 19:43:45
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:45:31
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Wheezing, LLT: Wheezing - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	23 Mar 2021 19:49:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 19:49:41
Data point term sent to Coder	System	23 Mar 2021 19:34:01
User entered 'Wheezing'	(b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User entered empty.	System	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User entered empty.	System	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User entered '0'	System	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57
User entered '0'	System	23 Mar 2021 19:33:28

US3372137

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:35:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:35:41
Data point term sent to Coder	System	23 Mar 2021 19:35:03
User entered 'Upper Respiratory Infection'	(b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User entered empty.	System	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '24 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User entered empty.	System	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User entered '0'	System	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07
User entered '0'	System	23 Mar 2021 19:34:13

US3372137

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:13:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:48:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:13:43

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:11
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:39:44
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:57:52
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 10:02:21
User signature succeeded.	Mira Baron (b) (4) (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:37:24

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 18:38:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:38:55
Data point term sent to Coder	System	01 Oct 2020 18:38:08
User entered 'escitalopram'	Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:00

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:38:00

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'depression'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:00

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered '20'	Peter Jacob (b) (4)	01 Oct 2020 18:38:00
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:38:00
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:00
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:38:00
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:00
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:00

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:00
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered 'un UNK 2008'	Peter Jacob (b) (4)	01 Oct 2020 18:38:00
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:00

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	01 Oct 2020 18:38:00
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:00
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:00

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 18:38:00

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 18:38:00

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 18:38:00

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 18:39:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:39:50
Data point term sent to Coder	System	01 Oct 2020 18:39:09
User entered 'escitalopram'	Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:26

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	01 Oct 2020 18:38:26
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'anxiety'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:26

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '20'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:26

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	01 Oct 2020 18:38:26
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:26
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:38:26
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:26
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:26

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:26
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered 'un UNK 2008'	Peter Jacob (b) (4)	01 Oct 2020 18:38:26
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:26

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	01 Oct 2020 18:38:26
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:26
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:38:26

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 18:38:26

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 18:38:26

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 18:38:26

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 18:39:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:39:49
Data point term sent to Coder	System	01 Oct 2020 18:39:09
User entered 'vitamin D3'	Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User closed query 'Per CDM: Please consider selecting "yes" for Prophylaxis, as the indication is "Dietary Supplement" or clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:41:58
Query 'Per CDM: Please consider selecting "yes" for Prophylaxis, as the indication is "Dietary Supplement" or clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 20:12:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 20:12:41
User opened query 'Per CDM: Please consider selecting "yes" for Prophylaxis, as the indication is "Dietary Supplement" or clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:48:08
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:47:17
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' answered with 'VITAMIN D3 IS RECOGNIZED AS AN DIETARY SUPPLEMENT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 18:43:54
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:44:44
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '20'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:55:06
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'DOSE UNIT IS CORRECT AS RECORDED ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 18:46:01
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:44:54
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:47
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered 'twice daily (BID)'	Peter Jacob (b) (4)	01 Oct 2020 18:38:47
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:47
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:38:47
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 18:38:47

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 20:20:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:20:51
Data point term sent to Coder	System	01 Oct 2020 18:40:10
User entered 'calcium/magnesium'	Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User closed query 'Per CDM Re-query: Please consider selecting 'yes' for Prophylaxis as the indication is dietary supplement, which is taken prophylactically. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:20
Query 'Per CDM Re-query: Please consider selecting 'yes' for Prophylaxis as the indication is dietary supplement, which is taken prophylactically. ' answered with 'dietary supplement is not an indication of prophylaxis use' (Site from DM).	Peter Jacob (b) (4) (b) (4)	18 Nov 2020 17:13:57
User opened query 'Per CDM Re-query: Please consider selecting 'yes' for Prophylaxis as the indication is dietary supplement, which is taken prophylactically. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:56:36
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:56:36
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' answered with 'CALCIUM/ MAGNESIUM IS RECOGINIZED AS AN DIETARY SUPPLEMENT' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 18:46:58
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:45:21
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '1500'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	01 Oct 2020 18:39:17
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:39:17
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'twice daily (BID)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:39:17
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:39:17
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered 'un UNK 2018'	Peter Jacob (b) (4)	01 Oct 2020 18:39:17
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	01 Oct 2020 18:39:17
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	01 Oct 2020 18:39:17
	(b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 18:39:17

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
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)	01 Oct 2020 18:40:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 18:40:48
Data point term sent to Coder	System	01 Oct 2020 18:40:13
User entered 'influenza vaccine'	Peter Jacob (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Oct 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'un Oct 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User entered empty.	System	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User entered empty.	System	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:47
User entered empty.	System	01 Oct 2020 18:39:39

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:05
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 17:49:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	15 Feb 2021 17:49:56
Data point term sent to Coder	System	15 Feb 2021 17:48:37
User entered 'Aspirin'	Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:07
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:09
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Cardiac Prophylaxis'	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:10
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '81'	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:12
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'mg (mg)'	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4)	15 Feb 2021 17:48:11
	Mary Sergalis (b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:16
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'once daily (QD)'	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:17
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4)	15 Feb 2021 17:48:11
	Mary Sergalis (b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Oral (ORAL)'	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:20
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:21
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '23 Jan 2021'	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered '0'	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:25
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered empty.	(b) (4)	15 Feb 2021 17:48:11
	Mary Sergalis (b) (4)	

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:46:28
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Feb 2021 17:48:11

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AMOXICLAV - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:53:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:53:00
User signature succeeded.	Mira Baron (b) (4) (b) (4)	23 Mar 2021 21:32:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AMOXICLAV - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 19:30:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 19:30:41
Data point term sent to Coder	System	23 Mar 2021 19:29:54
User entered 'Amoxiclav'	(b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Upper Respiratory Infection'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '875/125'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '24 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User entered '2'	System	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User entered '1'	System	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User entered '804 (804)'	System	23 Mar 2021 19:28:57

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 19:30:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 19:30:41
Data point term sent to Coder	System	23 Mar 2021 19:29:54
User entered 'Mucinex'	(b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Sinus Congestion'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '400'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User entered empty.	System	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User entered empty.	System	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:05:53
User entered empty.	System	23 Mar 2021 19:29:45

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:10:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:10:31
User signature succeeded.	Mira Baron (b) (4) (b) (4)	23 Mar 2021 21:32:35
Data point term sent to Coder	System	23 Mar 2021 19:30:55
User entered 'Tessalon Capsule'	(b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Cough'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '100'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User entered '3'	System	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User entered '1'	System	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:13:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:06:01
User entered '804 (804)'	System	23 Mar 2021 19:30:32

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:13:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:11
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:46:12
Signature has been broken.	Mary Sergalis (b) (4)	18 Mar 2021 15:25:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	18 Mar 2021 15:25:31
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
User entered 'No (N)'	Peter Jacob (b) (4)	01 Oct 2020 18:37:18

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:53
User entered '21 Jan 2021'	Mary Sergalis (b) (4)	18 Mar 2021 15:27:04

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:55
User entered 'MRI Cervical Spine'	Mary Sergalis (b) (4)	18 Mar 2021 15:27:04

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:56
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	18 Mar 2021 15:27:04

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:13:43

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:58
User entered empty.	Mary Sergalis (b) (4)	18 Mar 2021 15:27:04

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:01
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:55:43
User entered '21 Jan 2021'	Mary Sergalis (b) (4)	18 Mar 2021 15:32:25

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:01
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:55:45
User entered 'MRI Brain'	Mary Sergalis (b) (4)	18 Mar 2021 15:32:25

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:01
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:55:47
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	18 Mar 2021 15:32:25

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:13:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:01
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:55:48
User entered empty.	Mary Sergalis (b) (4)	18 Mar 2021 15:32:25

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:13:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:02
User closed query 'According to MR, date is 19Jan2021. Please review and clarify or reconcile. Thanks, (b) (6) ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 02:27:26
	(b) (4), (b) (6)	31 Mar 2021 02:27:24
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
Query 'According to MR, date is 19Jan2021. Please review and clarify or reconcile. Thanks, (b) (6) ' answered with 'Data updated' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 21:22:24
	(b) (4), (b) (6)	18 Mar 2021 21:22:15
User entered '19 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 21:22:15
User opened query 'According to MR, date is 19Jan2021. Please review and clarify or reconcile. Thanks, (b) (6) ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:57:18
	(b) (4), (b) (6)	18 Mar 2021 15:56:05
User entered '21 Jan 2021'	Mary Sergalis (b) (4)	18 Mar 2021 15:33:46

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:13:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:02
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:56:34
User entered 'CAT Head/Brain W/O Contrast'	Mary Sergalis (b) (4)	18 Mar 2021 15:33:46

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:02
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:56:36
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	18 Mar 2021 15:33:46

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:13:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:02
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:56:38
User entered empty.	Mary Sergalis (b) (4)	18 Mar 2021 15:33:46

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:13:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:03
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:58:10
User entered '19 Jan 2021'	Mary Sergalis (b) (4)	18 Mar 2021 15:34:35

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:13:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:03
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:58:12
User entered 'Chest X-Ray'	Mary Sergalis (b) (4)	18 Mar 2021 15:34:35

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:13:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:03
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:58:14
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	18 Mar 2021 15:34:35

US3372137

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:13:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:03
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:58:16
User entered empty.	Mary Sergalis (b) (4)	18 Mar 2021 15:34:35

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'USA-US056-2021-MRNA-1273-P301000004'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:15
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Yes (Y)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:17
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:18
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:20
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Yes (Y)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:23
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:26
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Mira'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:29
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Baron'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:30
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered '2277 Palm beach Lakes Blvd'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'West Palm Beach'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered '33409'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 01:24:35
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:36
User entered 'US'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 14:38:03
User entered '3'	System	19 Mar 2021 14:30:54
Signature has been broken.	System	26 Feb 2021 01:24:45
User entered '2'	System	26 Feb 2021 01:24:45
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered '1'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'USA-US056-2021-MRNA-1273-P301000004'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:15
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Yes (Y)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:17
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:18
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:20
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Yes (Y)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:23
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:26
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Mira'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:29
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Baron'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:30
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered '2277 Palm beach Lakes Blvd'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'West Palm Beach'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered '33409'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 01:24:35
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:36
User entered 'US'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 14:38:03
User entered '3'	System	19 Mar 2021 14:30:54
Signature has been broken.	System	26 Feb 2021 01:24:45
User entered '2'	System	26 Feb 2021 01:24:45
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered '1'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:13:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:43
User entered '27/Jan/2021 18:49'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:13:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 01:24:35
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:42
User entered 'I'	(b) (4), (b) (6)	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'USA-US056-2021-MRNA-1273-P301000004'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:15
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Yes (Y)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:17
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:18
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:20
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Yes (Y)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:23
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:26
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Mira'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:29
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Baron'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:30
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered '2277 Palm beach Lakes Blvd'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'West Palm Beach'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered '33409'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 01:24:35
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:36
User entered 'US'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 14:38:03
User entered '3'	System	19 Mar 2021 14:30:54
Signature has been broken.	System	26 Feb 2021 01:24:45
User entered '2'	System	26 Feb 2021 01:24:45
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered '1'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:13:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:43:45
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:33:16
User entered '26/Feb/2021 01:24'	(b) (4) System	26 Feb 2021 01:24:45

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:13:43

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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:43:45
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:30:37
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:33:16
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 01:24:45

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'USA-US056-2021-MRNA-1273-P301000004'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:15
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Yes (Y)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:17
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:18
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:20
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Yes (Y)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:23
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:26
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Mira'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:29
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Baron'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:30
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered '2277 Palm beach Lakes Blvd'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'West Palm Beach'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered '33409'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 01:24:35
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:36
User entered 'US'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 14:38:03
User entered '3'	System	19 Mar 2021 14:30:54
Signature has been broken.	System	26 Feb 2021 01:24:45
User entered '2'	System	26 Feb 2021 01:24:45
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered '1'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:13:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:43:45
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
User entered '19/Mar/2021 10:30'	(b) (4) System	19 Mar 2021 14:30:54

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:13:43

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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:43:45
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:38:08
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:30:33
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 14:30:54

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'USA-US056-2021-MRNA-1273-P301000004'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:15
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Yes (Y)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:17
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:18
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:20
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Yes (Y)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:23
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:26
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'No (N)'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Mira'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:29
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'Baron'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:30
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered '2277 Palm beach Lakes Blvd'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered 'West Palm Beach'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:34
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:49:26
User entered '33409'	System	27 Jan 2021 18:49:09

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 01:24:35
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:49:36
User entered 'US'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:13:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 14:38:03
User entered '3'	System	19 Mar 2021 14:30:54
Signature has been broken.	System	26 Feb 2021 01:24:45
User entered '2'	System	26 Feb 2021 01:24:45
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:19:22
	(b) (4)	
User entered '1'	System	27 Jan 2021 18:49:31

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:13:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:43:45
User signature succeeded.	Mira Baron (b) (4)	07 Apr 2021 18:53:11
User entered '07/Apr/2021 10:38'	(b) (4) System	07 Apr 2021 14:38:03

US3372137

Folder: SAE USA-US056-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:13:43

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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:43:45
User signature succeeded.	Mira Baron (b) (4)	07 Apr 2021 18:53:11
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:38:08
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 14:38:03