

US3292149 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:24:38

All time stamps listed in this document are displayed in GMT

US3292149

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 18:55:23

Generated On: 09 Jun 2021 16:24:38

[Participant ID](#)

US3292149

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

US3292149

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 22 Feb 2021 19:04:31

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Date of Informed Consent (<i>dd MMM yyyy</i>)	13 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) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 19:04:31

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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) 22 Feb 2021 19:04:31

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	COLON RESECTION
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	TWISTED COLON
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	SPHINCTEROTOMY - COLON
Start date (dd MMM yyyy)	UN APR 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	APR 2004
Start Year (derived)	2004
Stop Month and Year (derived)	APR 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	INGUINAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN DEC 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 DEC 2016
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2016
Start Year (derived)	2016
Stop Month and Year (derived)	DEC 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	EYE SURGERY - RIGHT EYE
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 (9)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	ROUTINE COLONOSCOPY
Start date (dd MMM yyyy)	UN OCT 2011
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 OCT 2011
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2011
Start Year (derived)	2011
Stop Month and Year (derived)	OCT 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	DECREASED VISUAL ACUITY
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 (13)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	HYPERCHOLESTEROLEMIA
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 (14)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	HYPERTENSION
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 (15)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	GENERALIZED ECZEMA
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 (16)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	ERECTILE DYSFUNCTION
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 (18)

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Condition	DRUG ALLERGY TO AMOXICILLIN
Start date (dd MMM yyyy)	UN AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	10:27 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:27
Height (xxx.x)	179.6 cm
Weight (xxx.x)	87.4 lb
BMI (xxx.x)	12.31618 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:04:31

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 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: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 19:04:31

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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

PATIENT GOES TO GYM 5
TIMES PER WEEK; HAS HIGH
BP, HIGH CHOLESTEROL AND
FORMER SMOKER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

PRODUCTION RELEASE (v12.003
EAB) (1725)

27 of 2419

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 19:04:31

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 185823

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) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

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) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

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)	13 AUG 2020
Time of assessment (00:00-23:59)	10:27 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:27
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)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

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)	13 AUG 2020
Time of assessment (00:00-23:59)	12:47 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 12:47
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 AUG 2020

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

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

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) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 AUG 2020

Collection time (00:00-23:59)

11:23 (24 HR)

Collection date and time (derived)

13 AUG 2020 11:23

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:38	13 AUG 2020 11:38
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

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 16:24:38

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

97.1 °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

13 AUG 2020 12:58

PC Open Date & Time

13 AUG 2020 12:32

PC Close Date & Time

13 AUG 2020 15:02

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

95.7 °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	13 AUG 2020 17:16
PC Open Date & Time	13 AUG 2020 15:57
PC Close Date & Time	14 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 16:45

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

15 AUG 2020 15:28

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

16 AUG 2020 15:33

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 16:56

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

18 AUG 2020 16:21

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 16:16

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:59

PC Open Date & Time

13 AUG 2020 12:32

PC Close Date & Time

13 AUG 2020 15:02

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 17:14

PC Open Date & Time

13 AUG 2020 15:57

PC Close Date & Time

14 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 16:46

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

15 AUG 2020 15:28

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 15:33

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 16:57

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 16:22

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 16:16

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 12:59
PC Open Date & Time	13 AUG 2020 12:32
PC Close Date & Time	13 AUG 2020 15:02

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 17:17
PC Open Date & Time	13 AUG 2020 15:57
PC Close Date & Time	14 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

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 ☒

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59 of 2419

EAB) (1725)

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 16:47
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 15:29
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

63 of 2419

EAB) (1725)

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 15:34
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

65 of 2419

EAB) (1725)

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 16:57
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

67 of 2419

EAB) (1725)

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 16:22
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

69 of 2419

EAB) (1725)

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 16:17
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3292149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292149

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

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)	12 SEP 2020
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 10:58
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)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

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)	12 SEP 2020
Time of assessment (00:00-23:59)	12:57 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 12:57
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3292149

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 SEP 2020

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

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

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) 12 SEP 2020

What was the treatment time? (00:00-23:59) 12:27 (24 HR)

Treatment Date and Time (derived) 12 SEP 2020 12:27

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

US3292149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 SEP 2020
Collection time (00:00-23:59)	11:13 (24 HR)
Collection date and time (derived)	12 SEP 2020 11:13

US3292149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Collection date (dd MMM yyyy)			12 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:28	12 SEP 2020 11:28
Nasopharyngeal Swab 2	No		

US3292149

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

97.0 °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

12 SEP 2020 13:01

PC Open Date & Time

12 SEP 2020 12:47

PC Close Date & Time

12 SEP 2020 15:17

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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 97.0 °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	12 SEP 2020 16:12
PC Open Date & Time	12 SEP 2020 16:12
PC Close Date & Time	13 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

97.2 °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

13 SEP 2020 14:20

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:30

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

95.0 °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

15 SEP 2020 14:43

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 15:28

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

94.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 15:21

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

97.8 °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

18 SEP 2020 14:07

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:47

PC Close Date & Time

12 SEP 2020 15:17

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

12 SEP 2020 16:13

PC Open Date & Time

12 SEP 2020 16:12

PC Close Date & Time

13 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

13 SEP 2020 14:21

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

14 SEP 2020 12:31

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

15 SEP 2020 14:43

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

16 SEP 2020 15:29

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 15:21

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

18 SEP 2020 14:07

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:47

PC Close Date & Time

12 SEP 2020 15:17

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 16:14
PC Open Date & Time	12 SEP 2020 16:12
PC Close Date & Time	13 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:31
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 14:44
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

111 of 2419

EAB) (1725)

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 15:29
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

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)

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 15:21
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 14:08
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3292149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292149

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292149

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292149

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	07:42 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 07:42
Temperature (xxx.x)	36.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292149

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

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.

US3292149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	07:54 (24 HR)
Collection date and time (derived)	8 OCT 2020 07:54

US3292149

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:04:32

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 OCT 2020 13:54:03
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

20 OCT 2020 08:15:29

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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	27 OCT 2020 08:39:00
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

10 NOV 2020 08:39:33

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

21 NOV 2020 15:24:47

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 07:06:04
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 18:43:42
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 07:51:26
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 10:24:42

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

26 DEC 2020 08:58:44

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 JAN 2021 08:30:59
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

09 JAN 2021 07:02:36

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

16 JAN 2021 09:11:10

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 07:50:00

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

30 JAN 2021 18:10:15

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	07 FEB 2021 11:59:29
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

13 FEB 2021 07:44:34

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 07:22:28

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 FEB 2021 07:15:19
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

06 MAR 2021 07:12:41

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 09:26:41

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 MAR 2021 14:59:38
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 MAR 2021 07:35:09
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

03 APR 2021 07:40:52

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

10 APR 2021 07:31:39

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 08:23:50

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 08:52:54

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 MAY 2021 08:26:57
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 <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"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

Patient Cloud Open Date & Time	02 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

Patient Cloud Open Date & Time	04 DEC 2021 00:01
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Patient Cloud Close Date & Time	08 DEC 2021 23:59
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US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 <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"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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="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"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

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08 JUN 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

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15 JUN 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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22 JUN 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

Date and time of submission

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25 JUN 2022 00:01

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29 JUN 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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06 JUL 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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09 JUL 2022 00:01

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13 JUL 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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20 JUL 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

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27 JUL 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

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03 AUG 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

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10 AUG 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

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20 AUG 2022 00:01

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24 AUG 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

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27 AUG 2022 00:01

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31 AUG 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

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03 SEP 2022 00:01

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07 SEP 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

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14 SEP 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

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17 SEP 2022 00:01

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21 SEP 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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"/>

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3292149

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:24:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 07:15:34

US3292149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292149

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292149

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 16:24:29

Generated On: 09 Jun 2021 16:24:38

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

Visit date (dd MMM yyyy)	15 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:24:29

Generated On: 09 Jun 2021 16:24:38

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) _____

US3292149

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 16:24:29

Generated On: 09 Jun 2021 16:24:38

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.

US3292149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 16:24:25

Generated On: 09 Jun 2021 16:24:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	08:54 (24 HR)
Collection date and time (derived)	15 MAR 2021 08:54

US3292149

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 16:24:25

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:04:18

Generated On: 09 Jun 2021 16:24:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292149

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:04:18

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292149

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:24:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3292149

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

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

Visit date (dd MMM yyyy)	12 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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US3292149

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 16:24:25

Generated On: 09 Jun 2021 16:24:38

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 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>)	12 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

US3292149

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

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

US3292149

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 11:45
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)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3292149

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 13:45
Temperature (xxx.x)	36.2 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)	180 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3292149

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3292149

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

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) 12 JAN 2021

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

Treatment Date and Time (derived) 12 JAN 2021 13:13

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

What was the frequency of the study treatment dosing? ONCE

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

US3292149

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	12:00 (24 HR)
Collection date and time (derived)	12 JAN 2021 12:00

US3292149

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	12:25
Collection Date and Time (derived)	12 JAN 2021 12:25

US3292149

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292149

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292149

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3292149

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

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)	9 FEB 2021
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 11:16
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

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)	9 FEB 2021
Time of assessment (00:00-23:59)	12:41 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 12:41
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3292149

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3292149

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 16:24:25

Generated On: 09 Jun 2021 16:24:38

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) 9 FEB 2021

What was the treatment time? (00:00-23:59) 12:09 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 12:09

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:04:31

Generated On: 09 Jun 2021 16:24:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 16:24:25

Generated On: 09 Jun 2021 16:24:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:24:25

Generated On: 09 Jun 2021 16:24:38

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) _____

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 16:24:25

Generated On: 09 Jun 2021 16:24:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 16:24:25

Generated On: 09 Jun 2021 16:24:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00-23:59)	10:56 (24 HR)
Collection date and time (derived)	9 MAR 2021 10:56

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 18:55:23

Generated On: 09 Jun 2021 16:24:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

AEID	USA-US072-2021-MRNA-1273-P30 1000013
Adverse event	SICK SINUS SYNDROME
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)	1 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	3 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	1 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	3 FEB 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:56:33

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Number of Days in ICU	2
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

PATIENT CONTACTED STAFF
ON SUNDAY, 07FEB2021 TO
REPORT A RECENT
HOSPITALIZATION THAT TOOK
PLACE 01FEB - 03FEB2021. PT
STATES HE WAS SITTING AT
HOME ON 01FEB WATCHING TV
WHEN HE BEGAN TO FEEL
NAUSEOUS. HE STATES HE
THEN PASSED OUT AND HIS
WIFE TOLD HIM HE WAS
UNRESPONSIVE FOR A FEW
MINUTES. 911 WAS CALLED
AND AMBULANCE TOOK HIM
TO ER. WHILE IN ER, PATIENT
STATES HE WAS TOLD HIS
HEART RHYTHM WAS
ABNORMAL. TUESDAY
MORNING, 02FEB, HE WAS
MOVED TO ICU AND
SCHEDULED TO HAVE
PACEMAKER PUT IN.
WEDNESDAY, 03FEB, PATIENT
WAS DISCHARGED IN STABLE
CONDITION. FOLLOW UP WITH
PCP AND CARDIOLOGIST
SCHEDULED. MEDICAL
RECORDS REQUESTED.
PATIENT STATES HE FEELS
"LIKE A MILLION BUCKS"
SINCE BEING DISCHARGED.

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)	1

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Persistent or significant disability or incapacity	
Congenital anomaly or birth defect	
Other medically important event	
Relationship to investigational product	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Relationship to Study Procedure	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Action taken with investigational product	None <input type="checkbox"/>
	Dose Delayed <input type="checkbox"/>
	Investigational Product <input type="checkbox"/>
	Withdrawn <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal <input type="checkbox"/>
	Not Recovered/Not Resolved <input type="checkbox"/>
	Recovered/Resolved <input type="checkbox"/>
	Recovered/Resolved with <input type="checkbox"/>
	Sequelae <input type="checkbox"/>
	Recovering/Resolving <input type="checkbox"/>
	Unknown <input type="checkbox"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	
Medically Attended AE Derived (CSA Programming Field Only)	
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) 22 Feb 2021 18:55:24

Generated On: 09 Jun 2021 16:24:38

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) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication HEART HEALTH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 2000

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication BENAZEPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	2 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication VIAGRA

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	INFLUENZA VACCINE
Dose per administration	0.5
Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	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)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication BENAZEPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	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)	3 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication NIFEDIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 5 APR 2021		
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 (11)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication CARDEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 3.125

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	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)	5 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (12)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication ATROPINE SULFATE

Prophylaxis Yes ☐
No ☒

Indication SICK SINUS SYNDROME

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	01 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	02 FEB 2021	
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 (13)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication ISUPREL

Prophylaxis Yes ☐
No ☒

Indication SICK SINUS SYNDROME

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	01 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	01 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication ENALAPRILET

Prophylaxis Yes ☐
No ☒

Indication SICK SINUS SYNDROME

Dose per administration 1.25

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 (14)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	01 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	03 FEB 2021	
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 (15)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SICK SINUS SYNDROME

Dose per administration 325

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 (15)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	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)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication SICK SINUS SYNDROME

Dose per administration 1000

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 (16)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	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 checked="" 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)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication SICK SINUS SYNDROME

Dose per administration 4

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 (17)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	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)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication SICK SINUS SYNDROME

Dose per administration 25

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify 5 TIMES

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2419

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 FEB 2021	
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"/>

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication VERSED

Prophylaxis Yes ☐
No ☒

Indication SICK SINUS SYNDROME

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

5 TIMES

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2419

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)		02 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 FEB 2021
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"/>

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

Name of Medication KEFZOL 1 GM

Prophylaxis Yes ☐
No ☒

Indication SICK SINUS SYNDROME

Dose per administration 1000

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)

399 of 2419

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 FEB 2021
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"/>

US3292149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 14:04:18

Generated On: 09 Jun 2021 16:24:38

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3292149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 14:04:18

Generated On: 09 Jun 2021 16:24:38

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 FEB 2021	PACE MAKER INSERTION	Adverse Event	

US3292149

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:24:38

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

US3292149

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:24:38

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 ☐

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

SAEID	USA-US072-2021-MRNA-1273-P301000013
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

SAEID	USA-US072-2021-MRNA-1273-P301000013
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/FEB/2021 13:27
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

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

SAEID	USA-US072-2021-MRNA-1273-P301000013
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/APR/2021 11:10
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

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 17:56:33

Generated On: 09 Jun 2021 16:24:38

SAEID	USA-US072-2021-MRNA-1273-P301000013
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/APR/2021 09:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3292149 (Prod: Clinical Trials of Texas, Inc)

US3292149

Form: Participant Creation

Generated On: 09 Jun 2021 16:24:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:14:22
User entered 'US3292149'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:39:47

US3292149

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:57:22

US3292149

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:39:48

US3292149

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 16:57:22

US3292149

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'SCRN'	System	14 Aug 2020 16:57:22

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:39:49

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '69'	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'YEARS'	System	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '70'	System	13 Aug 2020 17:26:53

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'I'	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:57:33

US3292149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 17:26:53

US3292149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Aug 2020'	System	13 Aug 2020 17:26:53

US3292149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2020'	System	13 Aug 2020 17:26:53

US3292149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 17:26:53

US3292149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:26:53

US3292149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:38

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:26:53

US3292149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:26:53

US3292149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 17:26:53

US3292149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:39:48

US3292149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'I'	System	13 Aug 2020 17:27:01

US3292149

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:27:01

US3292149

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:24:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:58:27

US3292149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:01:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:01:20
Data point term sent to Coder	System	14 Aug 2020 17:00:22
User entered 'Seasonal allergies'	(b) (4), (b) (6)	14 Aug 2020 16:59:50

US3292149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 16:59:50

US3292149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:59:50

US3292149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:59:50

US3292149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:59:50

US3292149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:59:50

US3292149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2015'	System	14 Aug 2020 16:59:50

US3292149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2015'	System	14 Aug 2020 16:59:50

US3292149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 16:59:50

US3292149

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 16:59:50

US3292149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Colectomy, LLT: Colectomy - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	14 Aug 2020 17:02:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:02:21
Data point term sent to Coder	System	14 Aug 2020 17:01:23
User entered 'Colon resection'	(b) (4), (b) (6)	14 Aug 2020 17:00:32

US3292149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2004'	(b) (4), (b) (6)	14 Aug 2020 17:00:32

US3292149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:00:32

US3292149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:00:32

US3292149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2004'	(b) (4), (b) (6)	14 Aug 2020 17:00:32

US3292149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:00:32

US3292149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2004'	System	14 Aug 2020 17:00:32

US3292149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2004'	System	14 Aug 2020 17:00:32

US3292149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2004'	System	14 Aug 2020 17:00:32

US3292149

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2004'	System	14 Aug 2020 17:00:32

US3292149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Volvulus, LLT: Volvulus of large bowel - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Sep 2020 12:57:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 12:57:54
Data point term sent to Coder	System	14 Aug 2020 17:01:26
User entered 'Twisted colon'	(b) (4), (b) (6)	14 Aug 2020 17:01:05

US3292149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2003'	(b) (4), (b) (6)	14 Aug 2020 17:01:05

US3292149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:01:05

US3292149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:01:05

US3292149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2004'	(b) (4), (b) (6)	14 Aug 2020 17:01:05

US3292149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:01:05

US3292149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2003'	System	14 Aug 2020 17:01:05

US3292149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2003'	System	14 Aug 2020 17:01:05

US3292149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2004'	System	14 Aug 2020 17:01:05

US3292149

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2004'	System	14 Aug 2020 17:01:05

US3292149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Anorectal therapeutic procedures, PT: Anal sphincterotomy, LLT: Anal sphincterotomy - version MedDRA\23.0.	Coder Import (b) (4)	26 Sep 2020 07:46:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Sep 2020 07:46:37
Data point term sent to Coder	System	18 Sep 2020 21:04:57
User closed query 'For coding purposes, please enter the location for SPHINCTEROTOMY in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	System	18 Sep 2020 21:04:25
Query 'For coding purposes, please enter the location for SPHINCTEROTOMY in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' answered with 'updated' (Site from System).	Gerardo Pena (b) (4)	18 Sep 2020 21:04:25
User entered 'SPHINCTEROTOMY - colon' reason for change: Data Entry Error	Gerardo Pena (b) (4)	18 Sep 2020 21:04:17
User opened query 'For coding purposes, please enter the location for SPHINCTEROTOMY in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4)	26 Aug 2020 23:19:29
Data point term sent to Coder	System	14 Aug 2020 17:03:31
User entered 'Sphincterotomy'	(b) (4), (b) (6)	14 Aug 2020 17:03:21

US3292149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Apr 2004'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:03:21

US3292149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:03:21

US3292149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:03:21

US3292149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Apr 2004'	(b) (4), (b) (6)	14 Aug 2020 17:03:21

US3292149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:03:21

US3292149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Apr 2004'	System	14 Aug 2020 17:03:21

US3292149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2004'	System	14 Aug 2020 17:03:21

US3292149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Apr 2004'	System	14 Aug 2020 17:03:21

US3292149

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2004'	System	14 Aug 2020 17:03:21

US3292149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Aug 2020 17:05:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:05:21
Data point term sent to Coder	System	14 Aug 2020 17:04:33
User entered 'Inguinal hernia repair'	(b) (4), (b) (6)	14 Aug 2020 17:04:20

US3292149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Dec 2016'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:04:20

US3292149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:04:20

US3292149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:04:20

US3292149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Dec 2016'	(b) (4), (b) (6)	14 Aug 2020 17:04:20

US3292149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:04:20

US3292149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Dec 2016'	System	14 Aug 2020 17:04:20

US3292149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2016'	System	14 Aug 2020 17:04:20

US3292149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Dec 2016'	System	14 Aug 2020 17:04:20

US3292149

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2016'	System	14 Aug 2020 17:04:20

US3292149

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Aug 2020 17:06:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:06:18
Data point term sent to Coder	System	14 Aug 2020 17:05:34
User entered 'Inguinal hernia'	(b) (4), (b) (6)	14 Aug 2020 17:05:01

US3292149

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2016'	(b) (4), (b) (6)	14 Aug 2020 17:05:01

US3292149

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:05:01

US3292149

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:05:01

US3292149

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2016'	(b) (4), (b) (6)	14 Aug 2020 17:05:01

US3292149

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:05:01

US3292149

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2016'	System	14 Aug 2020 17:05:01

US3292149

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2016'	System	14 Aug 2020 17:05:01

US3292149

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2016'	System	14 Aug 2020 17:05:01

US3292149

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2016'	System	14 Aug 2020 17:05:01

US3292149

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Eye therapeutic procedures NEC, PT: Eye operation, LLT: Eye operation - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:06:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:06:18
Data point term sent to Coder	System	14 Aug 2020 17:05:35
User entered 'Eye surgery'	(b) (4), (b) (6)	14 Aug 2020 17:05:28

US3292149

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Mar 2017'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:05:28

US3292149

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:05:28

US3292149

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:05:28

US3292149

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Mar 2017'	(b) (4), (b) (6)	14 Aug 2020 17:05:28

US3292149

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:05:28

US3292149

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Mar 2017'	System	14 Aug 2020 17:05:28

US3292149

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2017'	System	14 Aug 2020 17:05:28

US3292149

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Mar 2017'	System	14 Aug 2020 17:05:28

US3292149

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2017'	System	14 Aug 2020 17:05:28

US3292149

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Eye therapeutic procedures NEC, PT: Eye operation, LLT: Eye operation - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 00:20:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 00:20:56
Data point term sent to Coder	System	14 Aug 2020 17:06:36
User entered 'Eye surgery - right eye'	(b) (4), (b) (6)	14 Aug 2020 17:06:04

US3292149

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Jan 2020'	(b) (4), (b) (6)	14 Aug 2020 17:06:04

US3292149

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:06:04

US3292149

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:06:04

US3292149

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Jan 2020'	(b) (4), (b) (6)	14 Aug 2020 17:06:04

US3292149

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:06:04

US3292149

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2020'	System	14 Aug 2020 17:06:04

US3292149

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2020'	System	14 Aug 2020 17:06:04

US3292149

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2020'	System	14 Aug 2020 17:06:04

US3292149

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2020'	System	14 Aug 2020 17:06:04

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:10:55
' (Site from DM).		
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:21:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 15:21:47
Data point term sent to Coder	System	24 Sep 2020 15:21:08
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 15:20:33
' answered with 'updated' (Site from DM).		
Coding entries removed.	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 15:20:27
User entered 'routine COLONOSCOPY' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 15:20:27
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4), (b) (6)	22 Sep 2020 10:16:36
' (Site from DM).		
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:09:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:09:22
Data point term sent to Coder	System	14 Aug 2020 17:07:41

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
User entered 'Colonoscopy'	(b) (4), (b) (6)	14 Aug 2020 17:07:00

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Oct 2011'	(b) (4), (b) (6)	14 Aug 2020 17:07:00

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:07:00

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:07:00

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Oct 2011'	(b) (4), (b) (6)	14 Aug 2020 17:07:00

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:07:00

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Oct 2011'	System	14 Aug 2020 17:07:00

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2011'	System	14 Aug 2020 17:07:00

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Oct 2011'	System	14 Aug 2020 17:07:00

US3292149

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2011'	System	14 Aug 2020 17:07:00

US3292149

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Rhinitis, LLT: Rhinitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 17:09:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:09:22
Data point term sent to Coder	System	14 Aug 2020 17:07:42
User entered 'Rhinitis'	(b) (4), (b) (6)	14 Aug 2020 17:07:29

US3292149

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 17:07:29

US3292149

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:07:29

US3292149

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:07:29

US3292149

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:07:29

US3292149

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:07:29

US3292149

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2015'	System	14 Aug 2020 17:07:29

US3292149

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2015'	System	14 Aug 2020 17:07:29

US3292149

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:07:29

US3292149

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:07:29

US3292149

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate.	(b) (4), (b) (6)	08 Oct 2020 10:46:55
' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 15:21:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	24 Sep 2020 15:21:46
Data point term sent to Coder	System	24 Sep 2020 15:21:10
Query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate.	Dawn Killian (b) (4)	24 Sep 2020 15:21:09
' answered with 'updated' (Site from DM).	(b) (4)	
Coding entries removed.	Dawn Killian (b) (4)	24 Sep 2020 15:21:05
User entered 'bilateral CATARACTS' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate.	Dawn Killian (b) (4)	24 Sep 2020 15:21:05
' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:17:10
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:09:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	14 Aug 2020 17:09:23
Data point term sent to Coder	System	14 Aug 2020 17:08:44
User entered 'Cataracts'	(b) (4), (b) (6)	14 Aug 2020 17:08:01

US3292149

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2017'	(b) (4), (b) (6)	14 Aug 2020 17:08:01

US3292149

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:08:01

US3292149

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:08:01

US3292149

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2020'	(b) (4), (b) (6)	14 Aug 2020 17:08:01

US3292149

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:08:01

US3292149

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2017'	System	14 Aug 2020 17:08:01

US3292149

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2017'	System	14 Aug 2020 17:08:01

US3292149

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2020'	System	14 Aug 2020 17:08:01

US3292149

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2020'	System	14 Aug 2020 17:08:01

US3292149

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:09:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:09:23
Data point term sent to Coder	System	14 Aug 2020 17:08:45
User entered 'Decreased visual acuity'	(b) (4), (b) (6)	14 Aug 2020 17:08:25

US3292149

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2000'	(b) (4), (b) (6)	14 Aug 2020 17:08:25

US3292149

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:08:25

US3292149

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:08:25

US3292149

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:08:25

US3292149

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:08:25

US3292149

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2000'	System	14 Aug 2020 17:08:25

US3292149

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2000'	System	14 Aug 2020 17:08:25

US3292149

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:08:25

US3292149

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:08:25

US3292149

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Aug 2020 17:11:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:11:32
Data point term sent to Coder	System	14 Aug 2020 17:09:46
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	14 Aug 2020 17:08:47

US3292149

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2002'	(b) (4), (b) (6)	14 Aug 2020 17:08:47

US3292149

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:08:47

US3292149

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:08:47

US3292149

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:08:47

US3292149

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:08:47

US3292149

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2002'	System	14 Aug 2020 17:08:47

US3292149

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2002'	System	14 Aug 2020 17:08:47

US3292149

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:08:47

US3292149

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:08:47

US3292149

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Aug 2020 17:11:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:11:31
Data point term sent to Coder	System	14 Aug 2020 17:09:46
User entered 'Hypertension'	(b) (4), (b) (6)	14 Aug 2020 17:09:04

US3292149

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2002'	(b) (4), (b) (6)	14 Aug 2020 17:09:04

US3292149

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:09:04

US3292149

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:09:04

US3292149

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:09:04

US3292149

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:09:04

US3292149

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2002'	System	14 Aug 2020 17:09:04

US3292149

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2002'	System	14 Aug 2020 17:09:04

US3292149

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:09:04

US3292149

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:09:04

US3292149

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query 'Per DM CLR: Please specify the location of Eczema. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:47:13
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 15:22:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 15:22:50
Data point term sent to Coder	System	24 Sep 2020 15:22:11
Query 'Per DM CLR: Please specify the location of Eczema. Update Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 15:21:41
Coding entries removed.	Dawn Killian (b) (4)	24 Sep 2020 15:21:36
User entered 'generalized ECZEMA' reason for change: Data Entry Error	Dawn Killian (b) (4)	24 Sep 2020 15:21:36
User opened query 'Per DM CLR: Please specify the location of Eczema. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:17:29
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:11:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:11:31
Data point term sent to Coder	System	14 Aug 2020 17:09:47
User entered 'Eczema'	(b) (4), (b) (6)	14 Aug 2020 17:09:31

US3292149

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2008'	(b) (4), (b) (6)	14 Aug 2020 17:09:31

US3292149

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:09:31

US3292149

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:09:31

US3292149

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:09:31

US3292149

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:09:31

US3292149

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2008'	System	14 Aug 2020 17:09:31

US3292149

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2008'	System	14 Aug 2020 17:09:31

US3292149

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:09:31

US3292149

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:09:31

US3292149

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:11:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:11:33
Data point term sent to Coder	System	14 Aug 2020 17:10:49
User entered 'Benign prostatic hyperplasia'	(b) (4), (b) (6)	14 Aug 2020 17:10:42

US3292149

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 17:10:42

US3292149

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:10:42

US3292149

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:10:42

US3292149

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:10:42

US3292149

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:10:42

US3292149

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2015'	System	14 Aug 2020 17:10:42

US3292149

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2015'	System	14 Aug 2020 17:10:42

US3292149

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:10:42

US3292149

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:10:42

US3292149

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:12:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:12:28
Data point term sent to Coder	System	14 Aug 2020 17:11:51
User entered 'Erectile dysfunction'	(b) (4), (b) (6)	14 Aug 2020 17:11:03

US3292149

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un UNK 2008'	(b) (4), (b) (6)	14 Aug 2020 17:11:03

US3292149

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:11:03

US3292149

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:11:03

US3292149

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:11:03

US3292149

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:11:03

US3292149

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Jan 2008'	System	14 Aug 2020 17:11:03

US3292149

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2008'	System	14 Aug 2020 17:11:03

US3292149

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:11:03

US3292149

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	14 Aug 2020 17:11:03

US3292149

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
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: Allergy to antibiotic - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 22:14:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 22:14:14
Data point term sent to Coder	System	17 Aug 2020 18:15:53
User entered 'Drug allergy to amoxicillin'	(b) (4), (b) (6)	17 Aug 2020 18:15:10

US3292149

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'un Aug 2019'	(b) (4), (b) (6)	17 Aug 2020 18:15:10

US3292149

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 18:15:10

US3292149

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 18:15:10

US3292149

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 18:15:10

US3292149

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 18:15:10

US3292149

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'Aug 2019'	System	17 Aug 2020 18:15:10

US3292149

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '2019'	System	17 Aug 2020 18:15:10

US3292149

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	17 Aug 2020 18:15:10

US3292149

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	17 Aug 2020 18:15:10

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, time of assessment is required. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:37:07
Query 'Per CDM: Response noted; however per CCGs pages 15-16, time of assessment is required. Please update accordingly.' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	18 Sep 2020 21:07:01
User entered '10:27' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	18 Sep 2020 21:06:52
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, time of assessment is required. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 18:22:43
User closed query 'Data is required. Please provide.' (Site from System).		18 Aug 2020 06:54:21
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 17:20:58
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 17:20:52
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '13 Aug 2020 10:27'	System	18 Sep 2020 21:06:52
User entered empty.	System	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '179.6' cm	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:52
DataPoint set to visible.	System	13 Aug 2020 17:27:01

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '87.4' lb	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:52
DataPoint set to visible.	System	13 Aug 2020 17:27:01

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
Amendment Manager: User entered '12.31618'	System	16 Sep 2020 23:55:19
User entered '12.3'	System	14 Aug 2020 17:20:52
DataPoint set to visible.	System	13 Aug 2020 17:27:01

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'kg/m2'	System	14 Aug 2020 17:20:52
DataPoint set to visible.	System	13 Aug 2020 17:27:01

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query 'Per CDM: Please remove data and replace with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:05:36
Query 'Per CDM: Please remove data and replace with "ND" ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 17:51:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 17:51:50
User opened query 'Per CDM: Please remove data and replace with "ND" ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 16:36:17
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 16:36:17
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4)	18 Sep 2020 21:07:06
User entered '36.4' C reason for change: Data Entry Error	Gerardo Pena (b) (4)	18 Sep 2020 21:06:52
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 10:55:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 06:54:19
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 17:21:10
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 17:20:52
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query 'Per CDM: Please remove "other" as this field should be empty. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:05:38
Query 'Per CDM: Please remove "other" as this field should be empty. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 17:52:00
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4)	24 Sep 2020 17:51:50
User opened query 'Per CDM: Please remove "other" as this field should be empty. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 16:36:25
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 17:21:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Aug 2020 17:21:14
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 17:21:14
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 17:20:52
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty; reason for change Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	24 Sep 2020 17:51:50
	(b) (4)	
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	14 Aug 2020 17:21:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 17:21:22
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	14 Aug 2020 17:21:14
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query '□ Per CDM: Please remove data and replace with "ND" (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:05:41
Query '□ Per CDM: Please remove data and replace with "ND" answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 17:52:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 17:51:50
User opened query '□ Per CDM: Please remove data and replace with "ND" (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 16:36:48
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4)	4 Sep 2020 16:36:48
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4)	18 Sep 2020 21:07:11
User entered '55' reason for change: Data Entry Error	Gerardo Pena (b) (4)	18 Sep 2020 21:06:52
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 10:56:08
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 10:56:01
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 17:21:46
User opened query 'Data is required. Please provide.' System	(b) (4), (b) (6)	14 Aug 2020 17:20:52
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'bpm'	System	18 Sep 2020 21:06:52
User entered empty.	System	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query '□ Per CDM: Please remove data and replace with "ND" (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:05:44
Query '□ Per CDM: Please remove data and replace with "ND" answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 17:52:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 17:51:50
User opened query '□ Per CDM: Please remove data and replace with "ND" (Site from DM).	(b) (4), (b) (6)	4 Sep 2020 16:36:51
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	4 Sep 2020 16:36:51
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4)	18 Sep 2020 21:07:17
User entered '12' reason for change: Data Entry Error	Gerardo Pena (b) (4)	18 Sep 2020 21:06:52
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 10:56:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 10:56:10
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 17:21:44
User opened query 'Data is required. Please provide.' System	(b) (4), (b) (6)	14 Aug 2020 17:20:52
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'breaths/min'	System	18 Sep 2020 21:06:52
User entered empty.	System	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query 'Per CDM: Please remove data and replace with "ND" (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:05:46
Query 'Per CDM: Please remove data and replace with "ND" answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 17:52:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Sep 2020 17:51:50
User opened query 'Per CDM: Please remove data and replace with "ND" (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 16:36:55
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4)	24 Sep 2020 16:36:55
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4)	18 Sep 2020 21:07:23
User entered '153' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 21:06:52
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 10:56:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 10:56:15
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 17:21:42
User opened query 'Data is required. Please provide.' System	(b) (4), (b) (6)	14 Aug 2020 17:20:52
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'mmHg'	System	18 Sep 2020 21:06:52
User entered empty.	System	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query '□ Per CDM: Please remove data and replace with "ND" (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:05:48
Query '□ Per CDM: Please remove data and replace with "ND" answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 17:52:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User opened query '□ Per CDM: Please remove data and replace with "ND" (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 17:51:50
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 16:36:58
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4)	4 Sep 2020 16:36:58
User entered '86' reason for change: Data Entry Error	Gerardo Pena (b) (4)	18 Sep 2020 21:07:28
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	Gerardo Pena (b) (4)	18 Sep 2020 21:06:52
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 10:56:26
User opened query 'Data is required. Please provide.' System	(b) (4), (b) (6)	18 Aug 2020 10:56:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:21:40
		14 Aug 2020 17:20:52
		14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'mmHg'	System	18 Sep 2020 21:06:52
User entered empty.	System	14 Aug 2020 17:20:52

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23

US3292149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23

US3292149

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:22:24

US3292149

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 16:06:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		12 Sep 2020 18:18:55
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:22:24

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:24:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

[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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Patient goes to gym 5 times per week; has high BP, high cholesterol and former smoker'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

[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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'l'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:24:03

US3292149

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:24:15

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:24:15

US3292149

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[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 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 17:24:15

US3292149

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'VISIT1'	System	14 Aug 2020 17:24:15

US3292149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:54:35

US3292149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:10:51
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:10:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 16:54:35
User entered '185823' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:54:35

US3292149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:54:35

US3292149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:38

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 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query ' <input type="checkbox"/> PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:00:42
Query ' <input type="checkbox"/> PER CDM: Please complete this section of the form.' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	18 Sep 2020 21:01:09
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	18 Sep 2020 21:01:02
User opened query ' <input type="checkbox"/> PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 20:07:06

US3292149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:38

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 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	18 Sep 2020 21:01:02

US3292149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:38

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Sep 2020 21:01:02

US3292149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:38

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	18 Sep 2020 21:01:02

US3292149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	18 Sep 2020 21:01:02

US3292149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:41
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:01:18

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User accepted default value 'Pre-Dose (PREDOSE)'		14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '10:27'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '13 Aug 2020 10:27'	System	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '36.4' C	(b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '55'	(b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'bpm'	System	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12'	(b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'breaths/min'	System	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '153'	(b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'mmHg'	System	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '86'	(b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'mmHg'	System	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:57

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
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) (6)	18 Aug 2020 09:14:26
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'AS PER protocol post dose vitals can occur 30 minutes post dose' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:14:15
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).		14 Aug 2020 17:27:51
User entered '12:47'	(b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '13 Aug 2020 12:47'	System	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '36.2' C	(b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '56'	(b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'bpm'	System	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '16'	(b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'breaths/min'	System	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:33:37
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS as per investigator' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:14:24
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Aug 2020 17:27:51
User entered '169'	(b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'mmHg'	System	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '95'	(b) (4), (b) (6)	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'mmHg'	System	14 Aug 2020 17:27:51

US3292149

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:31:01

US3292149

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:31:01

US3292149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:33:17

US3292149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:33:17

US3292149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

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 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:33:17

US3292149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:33:17

US3292149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 17:33:17

US3292149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12:12'	(b) (4), (b) (6)	13 Aug 2020 17:33:17

US3292149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '13 Aug 2020 12:12'	System	13 Aug 2020 17:33:17

US3292149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Aug 2020 17:33:17

US3292149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'ONCE'	System	13 Aug 2020 17:33:17

US3292149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:33:17

US3292149

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:31:39

US3292149

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:31:39

US3292149

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '11:23'	(b) (4), (b) (6)	14 Aug 2020 17:31:39

US3292149

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '13 Aug 2020 11:23'	System	14 Aug 2020 17:31:39

US3292149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:24:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:31:59

US3292149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		14 Aug 2020 17:31:59

US3292149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:31:59

US3292149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '11:38'	(b) (4), (b) (6)	14 Aug 2020 17:31:59

US3292149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:38

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '13 Aug 2020 11:38'	System	14 Aug 2020 17:31:59

US3292149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Mar 2021 00:54:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		4 Aug 2020 17:32:07

US3292149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:32:07

US3292149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:32:07

US3292149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered empty.	System	14 Aug 2020 17:32:07

US3292149

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:32:20

US3292149

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'I'	System	14 Aug 2020 17:32:20

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:58:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '2ecce068-2b94-46d3-94fe-88d0496cddfa'	System	13 Aug 2020 17:58:35
User entered 'Yes (Y)'	System	13 Aug 2020 17:58:35

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:58:11', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '2ecce068-2b94-46d3-94fe-88d0496cddfa'	System	13 Aug 2020 17:58:35
User entered '97.1'	System	13 Aug 2020 17:58:35

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:58:19', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '2ecce068-2b94-46d3-94fe-88d0496cddfa'	System	13 Aug 2020 17:58:35
User entered 'No (N)'	System	13 Aug 2020 17:58:35

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:58:30', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '2ecce068-2b94-46d3-94fe-88d0496cddfa'	System	13 Aug 2020 17:58:35
User entered '13 Aug 2020 12:58'	System	13 Aug 2020 17:58:35

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Aug 2020 12:32'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Aug 2020 15:02'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:05', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3ec39065-335a-44ef-ad1f-a76fc3b839c7'	System	13 Aug 2020 22:16:30
User entered 'Yes (Y)'	System	13 Aug 2020 22:16:30

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:15', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3ec39065-335a-44ef-ad1f-a76fc3b839c7'	System	13 Aug 2020 22:16:30
User entered '95.7'	System	13 Aug 2020 22:16:30

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:20', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3ec39065-335a-44ef-ad1f-a76fc3b839c7'	System	13 Aug 2020 22:16:30
User entered 'No (N)'	System	13 Aug 2020 22:16:30

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:25', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3ec39065-335a-44ef-ad1f-a76fc3b839c7'	System	13 Aug 2020 22:16:30
User entered '13 Aug 2020 17:16'	System	13 Aug 2020 22:16:30

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Aug 2020 15:57'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 2'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:45:09', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8f8ef8c8-471b-46ca-bb1a-77c990580dcc'	System	14 Aug 2020 21:45:32
User entered 'Yes (Y)'	System	14 Aug 2020 21:45:32

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:45:19', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8f8ef8c8-471b-46ca-bb1a-77c990580dcc'	System	14 Aug 2020 21:45:32
User entered '95.5'	System	14 Aug 2020 21:45:32

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:45:24', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8f8ef8c8-471b-46ca-bb1a-77c990580dcc'	System	14 Aug 2020 21:45:32
User entered 'No (N)'	System	14 Aug 2020 21:45:32

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:45:29', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8f8ef8c8-471b-46ca-bb1a-77c990580dcc'	System	14 Aug 2020 21:45:32
User entered '14 Aug 2020 16:45'	System	14 Aug 2020 21:45:32

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 3'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:28:13', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '054146ab-cc27-40e0-a533-115e710e68e0'	System	15 Aug 2020 20:28:34
User entered 'Yes (Y)'	System	15 Aug 2020 20:28:34

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:28:22', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '054146ab-cc27-40e0-a533-115e710e68e0'	System	15 Aug 2020 20:28:34
User entered '96.6'	System	15 Aug 2020 20:28:34

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:28:26', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '054146ab-cc27-40e0-a533-115e710e68e0'	System	15 Aug 2020 20:28:34
User entered 'No (N)'	System	15 Aug 2020 20:28:34

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:28:31', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '054146ab-cc27-40e0-a533-115e710e68e0'	System	15 Aug 2020 20:28:34
User entered '15 Aug 2020 15:28'	System	15 Aug 2020 20:28:34

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 4'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:32:51', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8d47017a-9b9a-4475-8bb4-69b1ec473d84'	System	16 Aug 2020 20:33:11
User entered 'Yes (Y)'	System	16 Aug 2020 20:33:11

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:32:56', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8d47017a-9b9a-4475-8bb4-69b1ec473d84'	System	16 Aug 2020 20:33:11
User entered '96.6'	System	16 Aug 2020 20:33:11

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:03', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8d47017a-9b9a-4475-8bb4-69b1ec473d84'	System	16 Aug 2020 20:33:11
User entered 'No (N)'	System	16 Aug 2020 20:33:11

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:08', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8d47017a-9b9a-4475-8bb4-69b1ec473d84'	System	16 Aug 2020 20:33:11
User entered '16 Aug 2020 15:33'	System	16 Aug 2020 20:33:11

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 5'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:56:09', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f7d6862f-954d-4dfd-b033-1389fcb34d2b'	System	17 Aug 2020 21:56:45
User entered 'Yes (Y)'	System	17 Aug 2020 21:56:45

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:56:32', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f7d6862f-954d-4dfd-b033-1389fcb34d2b'	System	17 Aug 2020 21:56:45
User entered '96.4'	System	17 Aug 2020 21:56:45

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:56:38', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f7d6862f-954d-4dfd-b033-1389fcb34d2b'	System	17 Aug 2020 21:56:45
User entered 'No (N)'	System	17 Aug 2020 21:56:45

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:56:41', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f7d6862f-954d-4dfd-b033-1389fcb34d2b'	System	17 Aug 2020 21:56:45
User entered '17 Aug 2020 16:56'	System	17 Aug 2020 21:56:45

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 6'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:21:36', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f0034c59-d92d-4574-b348-909fe1b325cf'	System	18 Aug 2020 21:22:02
User entered 'Yes (Y)'	System	18 Aug 2020 21:22:02

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:21:48', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f0034c59-d92d-4574-b348-909fe1b325cf'	System	18 Aug 2020 21:22:02
User entered '97.2'	System	18 Aug 2020 21:22:02

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:21:52', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f0034c59-d92d-4574-b348-909fe1b325cf'	System	18 Aug 2020 21:22:02
User entered 'No (N)'	System	18 Aug 2020 21:22:02

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:21:56', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f0034c59-d92d-4574-b348-909fe1b325cf'	System	18 Aug 2020 21:22:02
User entered '18 Aug 2020 16:21'	System	18 Aug 2020 21:22:02

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 7'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:15:31', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c479fcc3-5ba1-4f32-bbce-8a6861a01e29'	System	19 Aug 2020 21:16:16
User entered 'Yes (Y)'	System	19 Aug 2020 21:16:16

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:03', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c479fcc3-5ba1-4f32-bbce-8a6861a01e29'	System	19 Aug 2020 21:16:16
User entered '96.8'	System	19 Aug 2020 21:16:16

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:08', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c479fcc3-5ba1-4f32-bbce-8a6861a01e29'	System	19 Aug 2020 21:16:16
User entered 'No (N)'	System	19 Aug 2020 21:16:16

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:12', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c479fcc3-5ba1-4f32-bbce-8a6861a01e29'	System	19 Aug 2020 21:16:16
User entered '19 Aug 2020 16:16'	System	19 Aug 2020 21:16:16

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:58:38', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6d4580fc-a85b-4e3f-ad64-f903f64f9aad'	System	13 Aug 2020 17:59:04
User entered 'None (1)'	System	13 Aug 2020 17:59:04

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:58:42', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6d4580fc-a85b-4e3f-ad64-f903f64f9aad'	System	13 Aug 2020 17:59:04
User entered 'No (N)'	System	13 Aug 2020 17:59:04

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:58:49', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6d4580fc-a85b-4e3f-ad64-f903f64f9aad'	System	13 Aug 2020 17:59:04
User entered 'No (N)'	System	13 Aug 2020 17:59:04

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:58:54', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6d4580fc-a85b-4e3f-ad64-f903f64f9aad'	System	13 Aug 2020 17:59:04
User entered 'None (1)'	System	13 Aug 2020 17:59:04

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:59:01', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6d4580fc-a85b-4e3f-ad64-f903f64f9aad'	System	13 Aug 2020 17:59:04
User entered '13 Aug 2020 12:59'	System	13 Aug 2020 17:59:04

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Aug 2020 12:32'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Aug 2020 15:02'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:13:14', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '1bbd8305-7482-4f94-9058-34060607d0ca'	System	13 Aug 2020 22:14:23
User entered 'None (1)'	System	13 Aug 2020 22:14:23

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:13:19', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '1bbd8305-7482-4f94-9058-34060607d0ca'	System	13 Aug 2020 22:14:23
User entered 'No (N)'	System	13 Aug 2020 22:14:23

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:13:24', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '1bbd8305-7482-4f94-9058-34060607d0ca'	System	13 Aug 2020 22:14:23
User entered 'No (N)'	System	13 Aug 2020 22:14:23

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:13:32', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '1bbd8305-7482-4f94-9058-34060607d0ca'	System	13 Aug 2020 22:14:23
User entered 'None (1)'	System	13 Aug 2020 22:14:23

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:14:18', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '1bbd8305-7482-4f94-9058-34060607d0ca'	System	13 Aug 2020 22:14:23
User entered '13 Aug 2020 17:14'	System	13 Aug 2020 22:14:23

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Aug 2020 15:57'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 2'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:46:01', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3fdd9520-00e4-457c-910f-9b01589b4630'	System	14 Aug 2020 21:46:53
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 21:46:53

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:46:12', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3fdd9520-00e4-457c-910f-9b01589b4630'	System	14 Aug 2020 21:46:53
User entered 'No (N)'	System	14 Aug 2020 21:46:53

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:46:28', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3fdd9520-00e4-457c-910f-9b01589b4630'	System	14 Aug 2020 21:46:53
User entered 'No (N)'	System	14 Aug 2020 21:46:53

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:46:36', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3fdd9520-00e4-457c-910f-9b01589b4630'	System	14 Aug 2020 21:46:53
User entered 'None (1)'	System	14 Aug 2020 21:46:53

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:46:49', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3fdd9520-00e4-457c-910f-9b01589b4630'	System	14 Aug 2020 21:46:53
User entered '14 Aug 2020 16:46'	System	14 Aug 2020 21:46:53

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 3'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:28:38', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '50b77d3f-b8e1-4f72-8771-2d68a1c929a8'	System	15 Aug 2020 20:28:56
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 20:28:56

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:28:42', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '50b77d3f-b8e1-4f72-8771-2d68a1c929a8'	System	15 Aug 2020 20:28:56
User entered 'No (N)'	System	15 Aug 2020 20:28:56

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:28:46', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '50b77d3f-b8e1-4f72-8771-2d68a1c929a8'	System	15 Aug 2020 20:28:56
User entered 'No (N)'	System	15 Aug 2020 20:28:56

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:28:50', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '50b77d3f-b8e1-4f72-8771-2d68a1c929a8'	System	15 Aug 2020 20:28:56
User entered 'None (1)'	System	15 Aug 2020 20:28:56

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:28:54', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '50b77d3f-b8e1-4f72-8771-2d68a1c929a8'	System	15 Aug 2020 20:28:56
User entered '15 Aug 2020 15:28'	System	15 Aug 2020 20:28:56

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 4'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:18', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '187b17ee-dba7-4841-902f-23f106cae42b'	System	16 Aug 2020 20:33:40
User entered 'None (1)'	System	16 Aug 2020 20:33:40

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:23', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '187b17ee-dba7-4841-902f-23f106cae42b'	System	16 Aug 2020 20:33:40
User entered 'No (N)'	System	16 Aug 2020 20:33:40

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:28', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '187b17ee-dba7-4841-902f-23f106cae42b'	System	16 Aug 2020 20:33:40
User entered 'No (N)'	System	16 Aug 2020 20:33:40

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:33', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '187b17ee-dba7-4841-902f-23f106cae42b'	System	16 Aug 2020 20:33:40
User entered 'None (1)'	System	16 Aug 2020 20:33:40

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:38', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '187b17ee-dba7-4841-902f-23f106cae42b'	System	16 Aug 2020 20:33:40
User entered '16 Aug 2020 15:33'	System	16 Aug 2020 20:33:40

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 5'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:56:49', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '31b5328e-6c7f-49c9-b450-1ad75d31af2c'	System	17 Aug 2020 21:57:11
User entered 'None (1)'	System	17 Aug 2020 21:57:11

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:56:55', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '31b5328e-6c7f-49c9-b450-1ad75d31af2c'	System	17 Aug 2020 21:57:11
User entered 'No (N)'	System	17 Aug 2020 21:57:11

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:56:59', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '31b5328e-6c7f-49c9-b450-1ad75d31af2c'	System	17 Aug 2020 21:57:11
User entered 'No (N)'	System	17 Aug 2020 21:57:11

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:57:03', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '31b5328e-6c7f-49c9-b450-1ad75d31af2c'	System	17 Aug 2020 21:57:11
User entered 'None (1)'	System	17 Aug 2020 21:57:11

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:57:07', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '31b5328e-6c7f-49c9-b450-1ad75d31af2c'	System	17 Aug 2020 21:57:11
User entered '17 Aug 2020 16:57'	System	17 Aug 2020 21:57:11

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 6'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:03', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '285e064e-4324-4809-9bf7-05fea83ace7e'	System	18 Aug 2020 21:22:24
User entered 'None (1)'	System	18 Aug 2020 21:22:24

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:07', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '285e064e-4324-4809-9bf7-05fea83ace7e'	System	18 Aug 2020 21:22:24
User entered 'No (N)'	System	18 Aug 2020 21:22:24

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:11', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '285e064e-4324-4809-9bf7-05fea83ace7e'	System	18 Aug 2020 21:22:24
User entered 'No (N)'	System	18 Aug 2020 21:22:24

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:17', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '285e064e-4324-4809-9bf7-05fea83ace7e'	System	18 Aug 2020 21:22:24
User entered 'None (1)'	System	18 Aug 2020 21:22:24

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:21', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '285e064e-4324-4809-9bf7-05fea83ace7e'	System	18 Aug 2020 21:22:24
User entered '18 Aug 2020 16:22'	System	18 Aug 2020 21:22:24

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 7'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:18', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c53c5548-a1db-40f8-8a0c-d19d2a5f843d'	System	19 Aug 2020 21:16:39
User entered 'None (1)'	System	19 Aug 2020 21:16:39

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:22', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c53c5548-a1db-40f8-8a0c-d19d2a5f843d'	System	19 Aug 2020 21:16:39
User entered 'No (N)'	System	19 Aug 2020 21:16:39

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:26', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c53c5548-a1db-40f8-8a0c-d19d2a5f843d'	System	19 Aug 2020 21:16:39
User entered 'No (N)'	System	19 Aug 2020 21:16:39

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:31', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c53c5548-a1db-40f8-8a0c-d19d2a5f843d'	System	19 Aug 2020 21:16:39
User entered 'None (1)'	System	19 Aug 2020 21:16:39

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:35', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c53c5548-a1db-40f8-8a0c-d19d2a5f843d'	System	19 Aug 2020 21:16:39
User entered '19 Aug 2020 16:16'	System	19 Aug 2020 21:16:39

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:59:11', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f8adefde-f128-4403-a568-478a4f902dc7'	System	13 Aug 2020 17:59:47
User entered 'None (0)'	System	13 Aug 2020 17:59:47

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:59:16', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f8adefde-f128-4403-a568-478a4f902dc7'	System	13 Aug 2020 17:59:47
User entered 'None (0)'	System	13 Aug 2020 17:59:47

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:59:20', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f8adefde-f128-4403-a568-478a4f902dc7'	System	13 Aug 2020 17:59:47
User entered 'None (0)'	System	13 Aug 2020 17:59:47

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:59:23', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f8adefde-f128-4403-a568-478a4f902dc7'	System	13 Aug 2020 17:59:47
User entered 'None (0)'	System	13 Aug 2020 17:59:47

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:59:27', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f8adefde-f128-4403-a568-478a4f902dc7'	System	13 Aug 2020 17:59:47
User entered 'None (0)'	System	13 Aug 2020 17:59:47

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:59:35', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f8adefde-f128-4403-a568-478a4f902dc7'	System	13 Aug 2020 17:59:47
User entered 'None (0)'	System	13 Aug 2020 17:59:47

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:59:41', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f8adefde-f128-4403-a568-478a4f902dc7'	System	13 Aug 2020 17:59:47
User entered 'No (N)'	System	13 Aug 2020 17:59:47

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T12:59:44', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f8adefde-f128-4403-a568-478a4f902dc7'	System	13 Aug 2020 17:59:47
User entered '13 Aug 2020 12:59'	System	13 Aug 2020 17:59:47

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Aug 2020 12:32'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Aug 2020 15:02'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:32', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6b3fd281-afc2-496f-afed-7f2fbca9eef4'	System	13 Aug 2020 22:17:06
User entered 'None (0)'	System	13 Aug 2020 22:17:06

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:37', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6b3fd281-afc2-496f-afed-7f2fbca9eef4'	System	13 Aug 2020 22:17:06
User entered 'None (0)'	System	13 Aug 2020 22:17:06

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:42', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6b3fd281-afc2-496f-afed-7f2fbca9eef4'	System	13 Aug 2020 22:17:06
User entered 'None (0)'	System	13 Aug 2020 22:17:06

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:46', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6b3fd281-afc2-496f-afed-7f2fbca9eef4'	System	13 Aug 2020 22:17:06
User entered 'None (0)'	System	13 Aug 2020 22:17:06

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:49', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6b3fd281-afc2-496f-afed-7f2fbca9eef4'	System	13 Aug 2020 22:17:06
User entered 'None (0)'	System	13 Aug 2020 22:17:06

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:52', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6b3fd281-afc2-496f-afed-7f2fbca9eef4'	System	13 Aug 2020 22:17:06
User entered 'None (0)'	System	13 Aug 2020 22:17:06

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:16:59', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6b3fd281-afc2-496f-afed-7f2fbca9eef4'	System	13 Aug 2020 22:17:06
User entered 'No (N)'	System	13 Aug 2020 22:17:06

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-13T17:17:04', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6b3fd281-afc2-496f-afed-7f2fbca9eef4'	System	13 Aug 2020 22:17:06
User entered '13 Aug 2020 17:17'	System	13 Aug 2020 22:17:06

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Aug 2020 15:57'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 2'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:46:57', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd85dcd04-b81c-42cd-81a7-c8bb10fa9afd'	System	14 Aug 2020 21:47:39
User entered 'None (0)'	System	14 Aug 2020 21:47:39

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:47:07', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd85dcd04-b81c-42cd-81a7-c8bb10fa9afd'	System	14 Aug 2020 21:47:39
User entered 'None (0)'	System	14 Aug 2020 21:47:39

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:47:11', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd85dcd04-b81c-42cd-81a7-c8bb10fa9afd'	System	14 Aug 2020 21:47:39
User entered 'None (0)'	System	14 Aug 2020 21:47:39

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:47:16', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd85dcd04-b81c-42cd-81a7-c8bb10fa9afd'	System	14 Aug 2020 21:47:39
User entered 'None (0)'	System	14 Aug 2020 21:47:39

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:47:19', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd85dcd04-b81c-42cd-81a7-c8bb10fa9afd'	System	14 Aug 2020 21:47:39
User entered 'None (0)'	System	14 Aug 2020 21:47:39

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:47:24', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd85dcd04-b81c-42cd-81a7-c8bb10fa9afd'	System	14 Aug 2020 21:47:39
User entered 'None (0)'	System	14 Aug 2020 21:47:39

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:47:30', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd85ded04-b81c-42cd-81a7-c8bb10fa9afd'	System	14 Aug 2020 21:47:39
User entered 'No (N)'	System	14 Aug 2020 21:47:39

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-14T16:47:33', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd85dcd04-b81c-42cd-81a7-c8bb10fa9afd'	System	14 Aug 2020 21:47:39
User entered '14 Aug 2020 16:47'	System	14 Aug 2020 21:47:39

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 3'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:29:01', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43fb3901-9a44-4be8-96b3-00be1d8d1488'	System	15 Aug 2020 20:29:27
User entered 'None (0)'	System	15 Aug 2020 20:29:27

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:29:04', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43fb3901-9a44-4be8-96b3-00be1d8d1488'	System	15 Aug 2020 20:29:27
User entered 'None (0)'	System	15 Aug 2020 20:29:27

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:29:07', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43fb3901-9a44-4be8-96b3-00be1d8d1488'	System	15 Aug 2020 20:29:27
User entered 'None (0)'	System	15 Aug 2020 20:29:27

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:29:10', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43fb3901-9a44-4be8-96b3-00be1d8d1488'	System	15 Aug 2020 20:29:27
User entered 'None (0)'	System	15 Aug 2020 20:29:27

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:29:13', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43fb3901-9a44-4be8-96b3-00be1d8d1488'	System	15 Aug 2020 20:29:27
User entered 'None (0)'	System	15 Aug 2020 20:29:27

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:29:17', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43fb3901-9a44-4be8-96b3-00be1d8d1488'	System	15 Aug 2020 20:29:27
User entered 'None (0)'	System	15 Aug 2020 20:29:27

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:29:22', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43fb3901-9a44-4be8-96b3-00be1d8d1488'	System	15 Aug 2020 20:29:27
User entered 'No (N)'	System	15 Aug 2020 20:29:27

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-15T15:29:25', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43fb3901-9a44-4be8-96b3-00be1d8d1488'	System	15 Aug 2020 20:29:27
User entered '15 Aug 2020 15:29'	System	15 Aug 2020 20:29:27

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 4'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:44', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49b4b0f5-21aa-4cbc-b24f-bdffc851eb77'	System	16 Aug 2020 20:34:14
User entered 'None (0)'	System	16 Aug 2020 20:34:14

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:47', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49b4b0f5-21aa-4cbc-b24f-bdffc851eb77'	System	16 Aug 2020 20:34:14
User entered 'None (0)'	System	16 Aug 2020 20:34:14

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:51', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49b4b0f5-21aa-4cbc-b24f-bdffc851eb77'	System	16 Aug 2020 20:34:14
User entered 'None (0)'	System	16 Aug 2020 20:34:14

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:55', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49b4b0f5-21aa-4cbc-b24f-bdffc851eb77'	System	16 Aug 2020 20:34:14
User entered 'None (0)'	System	16 Aug 2020 20:34:14

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:33:58', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49b4b0f5-21aa-4cbc-b24f-bdffc851eb77'	System	16 Aug 2020 20:34:14
User entered 'None (0)'	System	16 Aug 2020 20:34:14

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:34:01', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49b4b0f5-21aa-4cbc-b24f-bdffc851eb77'	System	16 Aug 2020 20:34:14
User entered 'None (0)'	System	16 Aug 2020 20:34:14

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:34:06', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49b4b0f5-21aa-4cbc-b24f-bdffc851eb77'	System	16 Aug 2020 20:34:14
User entered 'No (N)'	System	16 Aug 2020 20:34:14

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-16T15:34:10', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49b4b0f5-21aa-4cbc-b24f-bdffc851eb77'	System	16 Aug 2020 20:34:14
User entered '16 Aug 2020 15:34'	System	16 Aug 2020 20:34:14

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 5'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:57:13', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'e2625737-adf3-4a3e-95e5-ae4aa81eb190'	System	17 Aug 2020 21:57:38
User entered 'None (0)'	System	17 Aug 2020 21:57:38

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:57:16', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'e2625737-adf3-4a3e-95e5-ae4aa81eb190'	System	17 Aug 2020 21:57:38
User entered 'None (0)'	System	17 Aug 2020 21:57:38

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:57:19', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'e2625737-adf3-4a3e-95e5-ae4aa81eb190'	System	17 Aug 2020 21:57:38
User entered 'None (0)'	System	17 Aug 2020 21:57:38

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:57:22', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'e2625737-adf3-4a3e-95e5-ae4aa81eb190'	System	17 Aug 2020 21:57:38
User entered 'None (0)'	System	17 Aug 2020 21:57:38

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:57:25', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'e2625737-adf3-4a3e-95e5-ae4aa81eb190'	System	17 Aug 2020 21:57:38
User entered 'None (0)'	System	17 Aug 2020 21:57:38

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:57:28', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'e2625737-adf3-4a3e-95e5-ae4aa81eb190'	System	17 Aug 2020 21:57:38
User entered 'None (0)'	System	17 Aug 2020 21:57:38

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:57:32', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'e2625737-adf3-4a3e-95e5-ae4aa81eb190'	System	17 Aug 2020 21:57:38
User entered 'No (N)'	System	17 Aug 2020 21:57:38

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-17T16:57:35', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'e2625737-adf3-4a3e-95e5-ae4aa81eb190'	System	17 Aug 2020 21:57:38
User entered '17 Aug 2020 16:57'	System	17 Aug 2020 21:57:38

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 6'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:26', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9cabdd36-4885-4729-ac63-7f4bcb018a34'	System	18 Aug 2020 21:22:54
User entered 'None (0)'	System	18 Aug 2020 21:22:54

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:30', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9cabdd36-4885-4729-ac63-7f4bcb018a34'	System	18 Aug 2020 21:22:54
User entered 'None (0)'	System	18 Aug 2020 21:22:54

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:33', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9cabdd36-4885-4729-ac63-7f4bcb018a34'	System	18 Aug 2020 21:22:54
User entered 'None (0)'	System	18 Aug 2020 21:22:54

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:37', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9cabdd36-4885-4729-ac63-7f4bcb018a34'	System	18 Aug 2020 21:22:54
User entered 'None (0)'	System	18 Aug 2020 21:22:54

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:41', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9cabdd36-4885-4729-ac63-7f4bcb018a34'	System	18 Aug 2020 21:22:54
User entered 'None (0)'	System	18 Aug 2020 21:22:54

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:44', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9cabdd36-4885-4729-ac63-7f4bcb018a34'	System	18 Aug 2020 21:22:54
User entered 'None (0)'	System	18 Aug 2020 21:22:54

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:49', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9cabdd36-4885-4729-ac63-7f4bcb018a34'	System	18 Aug 2020 21:22:54
User entered 'No (N)'	System	18 Aug 2020 21:22:54

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-18T16:22:52', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9cabdd36-4885-4729-ac63-7f4bcb018a34'	System	18 Aug 2020 21:22:54
User entered '18 Aug 2020 16:22'	System	18 Aug 2020 21:22:54

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 7'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:41', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '53236fb0-1c32-4c3d-aa5a-8cc4efd3d151'	System	19 Aug 2020 21:17:15
User entered 'None (0)'	System	19 Aug 2020 21:17:15

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:44', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '53236fb0-1c32-4c3d-aa5a-8cc4efd3d151'	System	19 Aug 2020 21:17:15
User entered 'None (0)'	System	19 Aug 2020 21:17:15

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:48', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '53236fb0-1c32-4c3d-aa5a-8cc4efd3d151'	System	19 Aug 2020 21:17:15
User entered 'None (0)'	System	19 Aug 2020 21:17:15

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:51', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '53236fb0-1c32-4c3d-aa5a-8cc4efd3d151'	System	19 Aug 2020 21:17:15
User entered 'None (0)'	System	19 Aug 2020 21:17:15

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:54', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '53236fb0-1c32-4c3d-aa5a-8cc4efd3d151'	System	19 Aug 2020 21:17:15
User entered 'None (0)'	System	19 Aug 2020 21:17:15

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:16:57', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '53236fb0-1c32-4c3d-aa5a-8cc4efd3d151'	System	19 Aug 2020 21:17:15
User entered 'None (0)'	System	19 Aug 2020 21:17:15

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:17:05', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '53236fb0-1c32-4c3d-aa5a-8cc4efd3d151'	System	19 Aug 2020 21:17:15
User entered 'No (N)'	System	19 Aug 2020 21:17:15

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-08-19T16:17:08', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '53236fb0-1c32-4c3d-aa5a-8cc4efd3d151'	System	19 Aug 2020 21:17:15
User entered '19 Aug 2020 16:17'	System	19 Aug 2020 21:17:15

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:33:17

US3292149

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	21 Aug 2020 19:27:30

US3292149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '21 Aug 2020'	(b) (4) Kristy Trevino (b) (4) (b) (4)	21 Aug 2020 19:27:30

US3292149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	21 Aug 2020 19:27:30

US3292149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) Kristy Trevino (b) (4)	21 Aug 2020 19:27:30

US3292149

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	25 Aug 2020 02:10:15

US3292149

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'l'	System	25 Aug 2020 02:10:15

US3292149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Aug 2020 17:49:11

US3292149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '28 Aug 2020'	(b) (4) Kristy Trevino (b) (4) (b) (4)	28 Aug 2020 17:49:11

US3292149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	28 Aug 2020 17:49:11

US3292149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	28 Aug 2020 17:49:11

US3292149

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Aug 2020 17:49:19

US3292149

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'l'	System	28 Aug 2020 17:49:19

US3292149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	04 Sep 2020 15:47:10

US3292149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '4 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	04 Sep 2020 15:47:10

US3292149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	04 Sep 2020 15:47:10

US3292149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) Kristy Trevino (b) (4)	04 Sep 2020 15:47:10

US3292149

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	04 Sep 2020 15:47:17

US3292149

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'l'	System	04 Sep 2020 15:47:17

US3292149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:18:55

US3292149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12 Sep 2020'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:18:55

US3292149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[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 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Clinic (Clinic)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:18:55

US3292149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'VISIT2'	System	12 Sep 2020 18:18:55

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User accepted default value 'Pre-Dose (PREDOSE)'	Dawn Killian (b) (4) (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12 Sep 2020'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '10:58'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '12 Sep 2020 10:58'	System	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '36.3' C	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Oral (Oral)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '53'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'bpm'	System	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '14'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'breaths/min'	System	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '146'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'mmHg'	System	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '81'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'mmHg'	System	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User accepted default value 'Post-Dose (POSTDOSE)'	Dawn Killian (b) (4) (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12 Sep 2020'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12:57'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '12 Sep 2020 12:57'	System	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '36.1' C	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Oral (Oral)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '51'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'bpm'	System	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '16'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'breaths/min'	System	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 18:18:46
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per INV' (Site from System).	Dawn Killian (b) (4)	12 Sep 2020 18:20:22
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Sep 2020 18:20:11
User entered '158'	Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'mmHg'	System	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '89'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'mmHg'	System	12 Sep 2020 18:20:11

US3292149

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:33

US3292149

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12 Sep 2020'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:33

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 17:35:09

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 17:35:09

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

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 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 17:35:09

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'MRNA-1273 OR PLACEBO'	System	12 Sep 2020 17:35:09

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12 Sep 2020'	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 17:35:09

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12:27'	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 17:35:09

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '12 Sep 2020 12:27'	System	12 Sep 2020 17:35:09

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 17:35:09

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'ONCE'	System	12 Sep 2020 17:35:09

US3292149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'INTRAMUSCULAR'	System	12 Sep 2020 17:35:09

US3292149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:44

US3292149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12 Sep 2020'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:44

US3292149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '11:13'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:44

US3292149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '12 Sep 2020 11:13'	System	12 Sep 2020 18:20:44

US3292149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:24:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '12 Sep 2020'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:59

US3292149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dawn Killian (b) (4) (b) (4)	12 Sep 2020 18:20:59

US3292149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:59

US3292149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '11:28'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:59

US3292149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '12 Sep 2020 11:28'	System	12 Sep 2020 18:20:59

US3292149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dawn Killian (b) (4) (b) (4)	12 Sep 2020 18:20:59

US3292149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:59

US3292149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:20:59

US3292149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered empty.	System	12 Sep 2020 18:20:59

US3292149

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	12 Sep 2020 18:21:04

US3292149

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'I'	System	12 Sep 2020 18:21:04

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T13:00:50', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '19cbfd7c-2c83-455c-b398-082d229c1c8a'	System	12 Sep 2020 18:01:30
User entered 'Yes (Y)'	System	12 Sep 2020 18:01:30

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T13:00:59', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '19cbfd7c-2c83-455c-b398-082d229c1c8a'	System	12 Sep 2020 18:01:30
User entered '97.0'	System	12 Sep 2020 18:01:30

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T13:01:17', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '19cbfd7c-2c83-455c-b398-082d229c1c8a'	System	12 Sep 2020 18:01:30
User entered 'No (N)'	System	12 Sep 2020 18:01:30

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T13:01:27', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '19cbfd7c-2c83-455c-b398-082d229c1c8a'	System	12 Sep 2020 18:01:30
User entered '12 Sep 2020 13:01'	System	12 Sep 2020 18:01:30

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '12 Sep 2020 12:47'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '12 Sep 2020 15:17'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:12:39', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '123bad10-58be-41c4-a47a-9798e2cb8d4d'	System	12 Sep 2020 21:13:03
User entered 'Yes (Y)'	System	12 Sep 2020 21:13:03

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:12:48', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '123bad10-58be-41c4-a47a-9798e2cb8d4d' User entered '97.0'	System	12 Sep 2020 21:13:03
	System	12 Sep 2020 21:13:03

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:12:56', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '123bad10-58be-41c4-a47a-9798e2cb8d4d'	System	12 Sep 2020 21:13:03
User entered 'No (N)'	System	12 Sep 2020 21:13:03

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:12:59', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '123bad10-58be-41c4-a47a-9798e2cb8d4d'	System	12 Sep 2020 21:13:03
User entered '12 Sep 2020 16:12'	System	12 Sep 2020 21:13:03

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '12 Sep 2020 16:12'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 2'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:20:20', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '072c5155-c024-42f5-b4fc-49bab3220ee0'	System	13 Sep 2020 19:21:25
User entered 'Yes (Y)'	System	13 Sep 2020 19:21:25

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:20:33', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '072c5155-c024-42f5-b4fc-49bab3220ee0'	System	13 Sep 2020 19:21:25
User entered '97.2'	System	13 Sep 2020 19:21:25

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:20:37', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '072c5155-c024-42f5-b4fc-49bab3220ee0'	System	13 Sep 2020 19:21:25
User entered 'No (N)'	System	13 Sep 2020 19:21:25

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:20:44', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '072c5155-c024-42f5-b4fc-49bab3220ee0'	System	13 Sep 2020 19:21:25
User entered '13 Sep 2020 14:20'	System	13 Sep 2020 19:21:25

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 3'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:30:38', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8d2bd002-caa2-4772-91e5-41f896dce333'	System	14 Sep 2020 17:31:02
User entered 'Yes (Y)'	System	14 Sep 2020 17:31:02

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:30:47', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8d2bd002-caa2-4772-91e5-41f896dce333'	System	14 Sep 2020 17:31:02
User entered '96.8'	System	14 Sep 2020 17:31:02

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:30:51', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8d2bd002-caa2-4772-91e5-41f896dce333'	System	14 Sep 2020 17:31:02
User entered 'No (N)'	System	14 Sep 2020 17:31:02

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:30:55', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8d2bd002-caa2-4772-91e5-41f896dce333'	System	14 Sep 2020 17:31:02
User entered '14 Sep 2020 12:30'	System	14 Sep 2020 17:31:02

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 4'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:42:02', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c4b22ab2-4185-43a3-a8fa-a43a033247b0'	System	15 Sep 2020 19:43:06
User entered 'Yes (Y)'	System	15 Sep 2020 19:43:06

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:42:51', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c4b22ab2-4185-43a3-a8fa-a43a033247b0'	System	15 Sep 2020 19:43:06
User entered '95.0'	System	15 Sep 2020 19:43:06

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:42:57', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c4b22ab2-4185-43a3-a8fa-a43a033247b0'	System	15 Sep 2020 19:43:06
User entered 'No (N)'	System	15 Sep 2020 19:43:06

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:43:01', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c4b22ab2-4185-43a3-a8fa-a43a033247b0'	System	15 Sep 2020 19:43:06
User entered '15 Sep 2020 14:43'	System	15 Sep 2020 19:43:06

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 5'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:28:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6c23a121-b6a4-45ab-acc2-973dac3d856a'	System	16 Sep 2020 20:28:29
User entered 'Yes (Y)'	System	16 Sep 2020 20:28:29

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:28:17', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6c23a121-b6a4-45ab-acc2-973dac3d856a'	System	16 Sep 2020 20:28:29
User entered '96.4'	System	16 Sep 2020 20:28:29

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:28:21', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6c23a121-b6a4-45ab-acc2-973dac3d856a'	System	16 Sep 2020 20:28:29
User entered 'No (N)'	System	16 Sep 2020 20:28:29

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:28:27', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '6c23a121-b6a4-45ab-acc2-973dac3d856a'	System	16 Sep 2020 20:28:29
User entered '16 Sep 2020 15:28'	System	16 Sep 2020 20:28:29

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 6'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:20:45', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'a3f95bf3-7ea4-423f-bcae-8f30aaa8e7f2'	System	17 Sep 2020 20:21:07
User entered 'Yes (Y)'	System	17 Sep 2020 20:21:07

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:20:54', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'a3f95bf3-7ea4-423f-bcae-8f30aaa8e7f2'	System	17 Sep 2020 20:21:07
User entered '94.9'	System	17 Sep 2020 20:21:07

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:20:59', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'a3f95bf3-7ea4-423f-bcae-8f30aaa8e7f2'	System	17 Sep 2020 20:21:07
User entered 'No (N)'	System	17 Sep 2020 20:21:07

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:02', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'a3f95bf3-7ea4-423f-bcae-8f30aaa8e7f2'	System	17 Sep 2020 20:21:07
User entered '17 Sep 2020 15:21'	System	17 Sep 2020 20:21:07

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 7'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:07:09', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd50eddc b-90d9-4634-a507-5d0731e106ab'	System	18 Sep 2020 19:07:47
User entered 'Yes (Y)'	System	18 Sep 2020 19:07:47

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:07:29', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd50eddcB-90d9-4634-a507-5d0731e106ab' User entered '97.8'	System	18 Sep 2020 19:07:47
	System	18 Sep 2020 19:07:47

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:07:37', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd50eddcB-90d9-4634-a507-5d0731e106ab'	System	18 Sep 2020 19:07:47
User entered 'No (N)'	System	18 Sep 2020 19:07:47

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:07:41', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd50eddcB-90d9-4634-a507-5d0731e106ab'	System	18 Sep 2020 19:07:47
User entered '18 Sep 2020 14:07'	System	18 Sep 2020 19:07:47

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '12 Sep 2020 12:47'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '12 Sep 2020 15:17'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:08', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '1ae3ca82-3e7b-4b89-aae2-8ea0a33fa049'	System	12 Sep 2020 21:13:29
User entered 'None (1)'	System	12 Sep 2020 21:13:29

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:11', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '1ae3ca82-3e7b-4b89-aac2-8ea0a33fa049'	System	12 Sep 2020 21:13:29
User entered 'No (N)'	System	12 Sep 2020 21:13:29

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:16', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '1ae3ca82-3e7b-4b89-aac2-8ea0a33fa049'	System	12 Sep 2020 21:13:29
User entered 'No (N)'	System	12 Sep 2020 21:13:29

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:21', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '1ae3ca82-3e7b-4b89-aac2-8ea0a33fa049'	System	12 Sep 2020 21:13:29
User entered 'None (1)'	System	12 Sep 2020 21:13:29

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:25', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '1ae3ca82-3e7b-4b89-aac2-8ea0a33fa049'	System	12 Sep 2020 21:13:29
User entered '12 Sep 2020 16:13'	System	12 Sep 2020 21:13:29

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '12 Sep 2020 16:12'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 2'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:20:59', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '250e5d97-584c-4ab8-910e-9acf1164626e'	System	13 Sep 2020 19:21:38
User entered 'None (1)'	System	13 Sep 2020 19:21:38

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:21:05', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '250e5d97-584c-4ab8-910e-9acf1164626e'	System	13 Sep 2020 19:21:38
User entered 'No (N)'	System	13 Sep 2020 19:21:38

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:21:09', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '250e5d97-584c-4ab8-910e-9acf1164626e'	System	13 Sep 2020 19:21:38
User entered 'No (N)'	System	13 Sep 2020 19:21:38

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:21:22', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '250e5d97-584c-4ab8-910e-9acf1164626e'	System	13 Sep 2020 19:21:38
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 19:21:38

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:21:27', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '250e5d97-584c-4ab8-910e-9acf1164626e'	System	13 Sep 2020 19:21:38
User entered '13 Sep 2020 14:21'	System	13 Sep 2020 19:21:38

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 3'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:04', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '067243c1-ffbd-4a96-84d4-68553c3745ab'	System	14 Sep 2020 17:31:21
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 17:31:21

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:08', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '067243c1-ffbd-4a96-84d4-68553c3745ab'	System	14 Sep 2020 17:31:21
User entered 'No (N)'	System	14 Sep 2020 17:31:21

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:11', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '067243c1-ffbd-4a96-84d4-68553c3745ab'	System	14 Sep 2020 17:31:21
User entered 'No (N)'	System	14 Sep 2020 17:31:21

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:15', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '067243c1-ffbd-4a96-84d4-68553c3745ab'	System	14 Sep 2020 17:31:21
User entered 'None (1)'	System	14 Sep 2020 17:31:21

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:18', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '067243c1-ffbd-4a96-84d4-68553c3745ab'	System	14 Sep 2020 17:31:21
User entered '14 Sep 2020 12:31'	System	14 Sep 2020 17:31:21

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 4'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:43:07', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49ceb8e9-1682-41c7-9e4d-496fb323074d'	System	15 Sep 2020 19:43:29
User entered 'None (1)'	System	15 Sep 2020 19:43:29

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:43:11', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49ceb8e9-1682-41c7-9e4d-496fb323074d'	System	15 Sep 2020 19:43:29
User entered 'No (N)'	System	15 Sep 2020 19:43:29

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:43:15', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49ceb8e9-1682-41c7-9e4d-496fb323074d'	System	15 Sep 2020 19:43:29
User entered 'No (N)'	System	15 Sep 2020 19:43:29

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:43:22', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49ceb8e9-1682-41c7-9e4d-496fb323074d'	System	15 Sep 2020 19:43:29
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 19:43:29

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:43:25', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '49ceb8e9-1682-41c7-9e4d-496fb323074d'	System	15 Sep 2020 19:43:29
User entered '15 Sep 2020 14:43'	System	15 Sep 2020 19:43:29

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 5'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:28:42', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b7b8e998-6266-4102-9067-2b166c243ae5'	System	16 Sep 2020 20:29:04
User entered 'None (1)'	System	16 Sep 2020 20:29:04

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:28:46', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b7b8e998-6266-4102-9067-2b166c243ae5'	System	16 Sep 2020 20:29:04
User entered 'No (N)'	System	16 Sep 2020 20:29:04

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:28:51', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b7b8e998-6266-4102-9067-2b166c243ae5'	System	16 Sep 2020 20:29:04
User entered 'No (N)'	System	16 Sep 2020 20:29:04

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:28:57', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b7b8e998-6266-4102-9067-2b166c243ae5'	System	16 Sep 2020 20:29:04
User entered 'None (1)'	System	16 Sep 2020 20:29:04

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:29:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b7b8e998-6266-4102-9067-2b166c243ae5'	System	16 Sep 2020 20:29:04
User entered '16 Sep 2020 15:29'	System	16 Sep 2020 20:29:04

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 6'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:07', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '45cbe150-9a09-4928-9513-700dd39fb45a'	System	17 Sep 2020 20:21:26
User entered 'None (1)'	System	17 Sep 2020 20:21:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:11', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '45cbe150-9a09-4928-9513-700dd39fb45a'	System	17 Sep 2020 20:21:26
User entered 'No (N)'	System	17 Sep 2020 20:21:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:15', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '45cbe150-9a09-4928-9513-700dd39fb45a'	System	17 Sep 2020 20:21:26
User entered 'No (N)'	System	17 Sep 2020 20:21:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:20', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '45cbe150-9a09-4928-9513-700dd39fb45a'	System	17 Sep 2020 20:21:26
User entered 'None (1)'	System	17 Sep 2020 20:21:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:23', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '45cbe150-9a09-4928-9513-700dd39fb45a'	System	17 Sep 2020 20:21:26
User entered '17 Sep 2020 15:21'	System	17 Sep 2020 20:21:26

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 7'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:07:46', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dbecfb0b-cac1-4f21-a682-c52575b48ea9'	System	18 Sep 2020 19:08:03
User entered 'None (1)'	System	18 Sep 2020 19:08:03

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:07:49', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dbecfb0b-cac1-4f21-a682-c52575b48ea9'	System	18 Sep 2020 19:08:03
User entered 'No (N)'	System	18 Sep 2020 19:08:03

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:07:52', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dbecfb0b-cac1-4f21-a682-c52575b48ea9'	System	18 Sep 2020 19:08:03
User entered 'No (N)'	System	18 Sep 2020 19:08:03

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:07:56', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dbecfb0b-cac1-4f21-a682-c52575b48ea9'	System	18 Sep 2020 19:08:03
User entered 'None (1)'	System	18 Sep 2020 19:08:03

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:07:58', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dbecfb0b-cac1-4f21-a682-c52575b48ea9'	System	18 Sep 2020 19:08:03
User entered '18 Sep 2020 14:07'	System	18 Sep 2020 19:08:03

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '12 Sep 2020 12:47'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '12 Sep 2020 15:17'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:34', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ae687eeb-8e0f-469a-a608-acd26dd52b90'	System	12 Sep 2020 21:14:06
User entered 'None (0)'	System	12 Sep 2020 21:14:06

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:39', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ae687eeb-8e0f-469a-a608-acd26dd52b90'	System	12 Sep 2020 21:14:06
User entered 'None (0)'	System	12 Sep 2020 21:14:06

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:42', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ae687eeb-8e0f-469a-a608-acd26dd52b90'	System	12 Sep 2020 21:14:06
User entered 'None (0)'	System	12 Sep 2020 21:14:06

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:45', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ae687eeb-8e0f-469a-a608-acd26dd52b90'	System	12 Sep 2020 21:14:06
User entered 'None (0)'	System	12 Sep 2020 21:14:06

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:50', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ae687eeb-8e0f-469a-a608-acd26dd52b90'	System	12 Sep 2020 21:14:06
User entered 'None (0)'	System	12 Sep 2020 21:14:06

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:53', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ae687eeb-8e0f-469a-a608-acd26dd52b90'	System	12 Sep 2020 21:14:06
User entered 'None (0)'	System	12 Sep 2020 21:14:06

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:13:58', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ae687eeb-8e0f-469a-a608-acd26dd52b90'	System	12 Sep 2020 21:14:06
User entered 'No (N)'	System	12 Sep 2020 21:14:06

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-12T16:14:02', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ae687eeb-8e0f-469a-a608-acd26dd52b90'	System	12 Sep 2020 21:14:06
User entered '12 Sep 2020 16:14'	System	12 Sep 2020 21:14:06

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '12 Sep 2020 16:12'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 2'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:21:41', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b13fd024-a02f-4ab0-89de-8b31513b6d62'	System	13 Sep 2020 19:22:27
User entered 'None (0)'	System	13 Sep 2020 19:22:27

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:21:44', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b13fd024-a02f-4ab0-89de-8b31513b6d62'	System	13 Sep 2020 19:22:27
User entered 'None (0)'	System	13 Sep 2020 19:22:27

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:21:57', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b13fd024-a02f-4ab0-89de-8b31513b6d62'	System	13 Sep 2020 19:22:27
User entered 'No interference with activity (1)'	System	13 Sep 2020 19:22:27

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:22:04', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b13fd024-a02f-4ab0-89de-8b31513b6d62'	System	13 Sep 2020 19:22:27
User entered 'None (0)'	System	13 Sep 2020 19:22:27

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:22:10', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b13fd024-a02f-4ab0-89de-8b31513b6d62'	System	13 Sep 2020 19:22:27
User entered 'None (0)'	System	13 Sep 2020 19:22:27

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:22:13', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b13fd024-a02f-4ab0-89de-8b31513b6d62'	System	13 Sep 2020 19:22:27
User entered 'None (0)'	System	13 Sep 2020 19:22:27

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:22:18', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b13fd024-a02f-4ab0-89de-8b31513b6d62'	System	13 Sep 2020 19:22:27
User entered 'No (N)'	System	13 Sep 2020 19:22:27

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-13T14:22:24', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b13fd024-a02f-4ab0-89de-8b31513b6d62'	System	13 Sep 2020 19:22:27
User entered '13 Sep 2020 14:22'	System	13 Sep 2020 19:22:27

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 3'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:24', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f84cef14-1ddb-4951-9de1-b7f6338f7d55'	System	14 Sep 2020 17:31:53
User entered 'None (0)'	System	14 Sep 2020 17:31:53

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:29', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f84cef14-1ddb-4951-9de1-b7f6338f7d55'	System	14 Sep 2020 17:31:53
User entered 'None (0)'	System	14 Sep 2020 17:31:53

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:33', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f84cef14-1ddb-4951-9de1-b7f6338f7d55'	System	14 Sep 2020 17:31:53
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:31:53

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:37', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f84cef14-1ddb-4951-9de1-b7f6338f7d55'	System	14 Sep 2020 17:31:53
User entered 'None (0)'	System	14 Sep 2020 17:31:53

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:40', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f84cef14-1ddb-4951-9de1-b7f6338f7d55'	System	14 Sep 2020 17:31:53
User entered 'None (0)'	System	14 Sep 2020 17:31:53

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:43', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f84cef14-1ddb-4951-9de1-b7f6338f7d55'	System	14 Sep 2020 17:31:53
User entered 'None (0)'	System	14 Sep 2020 17:31:53

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:47', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f84cef14-1ddb-4951-9de1-b7f6338f7d55'	System	14 Sep 2020 17:31:53
User entered 'No (N)'	System	14 Sep 2020 17:31:53

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-14T12:31:51', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f84cef14-1ddb-4951-9de1-b7f6338f7d55'	System	14 Sep 2020 17:31:53
User entered '14 Sep 2020 12:31'	System	14 Sep 2020 17:31:53

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 4'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:43:30', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fafb43ad-6294-4492-ac48-a3533f68d22f'	System	15 Sep 2020 19:44:18
User entered 'None (0)'	System	15 Sep 2020 19:44:18

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:43:34', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fafb43ad-6294-4492-ac48-a3533f68d22f'	System	15 Sep 2020 19:44:18
User entered 'None (0)'	System	15 Sep 2020 19:44:18

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:43:42', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fafb43ad-6294-4492-ac48-a3533f68d22f'	System	15 Sep 2020 19:44:18
User entered 'None (0)'	System	15 Sep 2020 19:44:18

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:43:58', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fafb43ad-6294-4492-ac48-a3533f68d22f'	System	15 Sep 2020 19:44:18
User entered 'None (0)'	System	15 Sep 2020 19:44:18

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:44:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fafb43ad-6294-4492-ac48-a3533f68d22f'	System	15 Sep 2020 19:44:18
User entered 'None (0)'	System	15 Sep 2020 19:44:18

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:44:04', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fafb43ad-6294-4492-ac48-a3533f68d22f'	System	15 Sep 2020 19:44:18
User entered 'None (0)'	System	15 Sep 2020 19:44:18

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:44:09', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fafb43ad-6294-4492-ac48-a3533f68d22f'	System	15 Sep 2020 19:44:18
User entered 'No (N)'	System	15 Sep 2020 19:44:18

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-15T14:44:12', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fafb43ad-6294-4492-ac48-a3533f68d22f'	System	15 Sep 2020 19:44:18
User entered '15 Sep 2020 14:44'	System	15 Sep 2020 19:44:18

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 5'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:29:07', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3a9139da-2ee5-45bd-9bf2-5bfe2e7d2a44'	System	16 Sep 2020 20:29:31
User entered 'None (0)'	System	16 Sep 2020 20:29:31

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:29:10', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3a9139da-2ee5-45bd-9bf2-5bfe2e7d2a44'	System	16 Sep 2020 20:29:31
User entered 'None (0)'	System	16 Sep 2020 20:29:31

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:29:12', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3a9139da-2ee5-45bd-9bf2-5bfe2e7d2a44'	System	16 Sep 2020 20:29:31
User entered 'None (0)'	System	16 Sep 2020 20:29:31

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:29:15', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3a9139da-2ee5-45bd-9bf2-5bfe2e7d2a44'	System	16 Sep 2020 20:29:31
User entered 'None (0)'	System	16 Sep 2020 20:29:31

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:29:18', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3a9139da-2ee5-45bd-9bf2-5bfe2e7d2a44'	System	16 Sep 2020 20:29:31
User entered 'None (0)'	System	16 Sep 2020 20:29:31

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:29:21', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3a9139da-2ee5-45bd-9bf2-5bfe2e7d2a44'	System	16 Sep 2020 20:29:31
User entered 'None (0)'	System	16 Sep 2020 20:29:31

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:29:26', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3a9139da-2ee5-45bd-9bf2-5bfe2e7d2a44'	System	16 Sep 2020 20:29:31
User entered 'No (N)'	System	16 Sep 2020 20:29:31

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-16T15:29:29', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '3a9139da-2ee5-45bd-9bf2-5bfe2e7d2a44'	System	16 Sep 2020 20:29:31
User entered '16 Sep 2020 15:29'	System	16 Sep 2020 20:29:31

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 6'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:29', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dffd3a23-d519-496f-a140-bef8cd0b2af2'	System	17 Sep 2020 20:21:57
User entered 'None (0)'	System	17 Sep 2020 20:21:57

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:33', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dffd3a23-d519-496f-a140-bef8cd0b2af2'	System	17 Sep 2020 20:21:57
User entered 'None (0)'	System	17 Sep 2020 20:21:57

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:36', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dffd3a23-d519-496f-a140-bef8cd0b2af2'	System	17 Sep 2020 20:21:57
User entered 'None (0)'	System	17 Sep 2020 20:21:57

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:38', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dffd3a23-d519-496f-a140-bef8cd0b2af2'	System	17 Sep 2020 20:21:57
User entered 'None (0)'	System	17 Sep 2020 20:21:57

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:41', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dffd3a23-d519-496f-a140-bef8cd0b2af2'	System	17 Sep 2020 20:21:57
User entered 'None (0)'	System	17 Sep 2020 20:21:57

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:44', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dffd3a23-d519-496f-a140-bef8cd0b2af2'	System	17 Sep 2020 20:21:57
User entered 'None (0)'	System	17 Sep 2020 20:21:57

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:50', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dffd3a23-d519-496f-a140-bef8cd0b2af2'	System	17 Sep 2020 20:21:57
User entered 'No (N)'	System	17 Sep 2020 20:21:57

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-17T15:21:53', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'dffd3a23-d519-496f-a140-bef8cd0b2af2'	System	17 Sep 2020 20:21:57
User entered '17 Sep 2020 15:21'	System	17 Sep 2020 20:21:57

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	12 Sep 2020 17:35:09
User entered 'Day 7'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:08:07', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8a7f9ff0-e8e3-4bc9-b536-0fa016f3ce93'	System	18 Sep 2020 19:08:40
User entered 'None (0)'	System	18 Sep 2020 19:08:40

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:08:10', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8a7f9ff0-e8e3-4bc9-b536-0fa016f3ce93'	System	18 Sep 2020 19:08:40
User entered 'None (0)'	System	18 Sep 2020 19:08:40

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:08:15', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8a7f9ff0-e8e3-4bc9-b536-0fa016f3ce93'	System	18 Sep 2020 19:08:40
User entered 'None (0)'	System	18 Sep 2020 19:08:40

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:08:18', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8a7f9ff0-e8e3-4bc9-b536-0fa016f3ce93'	System	18 Sep 2020 19:08:40
User entered 'None (0)'	System	18 Sep 2020 19:08:40

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:08:21', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8a7f9ff0-e8e3-4bc9-b536-0fa016f3ce93'	System	18 Sep 2020 19:08:40
User entered 'None (0)'	System	18 Sep 2020 19:08:40

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:08:24', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8a7f9ff0-e8e3-4bc9-b536-0fa016f3ce93'	System	18 Sep 2020 19:08:40
User entered 'None (0)'	System	18 Sep 2020 19:08:40

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:08:32', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8a7f9ff0-e8e3-4bc9-b536-0fa016f3ce93'	System	18 Sep 2020 19:08:40
User entered 'No (N)'	System	18 Sep 2020 19:08:40

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-09-18T14:08:36', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '8a7f9ff0-e8e3-4bc9-b536-0fa016f3ce93'	System	18 Sep 2020 19:08:40
User entered '18 Sep 2020 14:08'	System	18 Sep 2020 19:08:40

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:35:09

US3292149

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:35:09

US3292149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	21 Sep 2020 19:42:59

US3292149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '21 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	21 Sep 2020 19:42:59

US3292149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	21 Sep 2020 19:42:59

US3292149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) Kristy Trevino (b) (4)	21 Sep 2020 19:42:59

US3292149

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	21 Sep 2020 19:47:57

US3292149

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'l'	System	21 Sep 2020 19:47:57

US3292149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 19:31:07

US3292149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '28 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 19:31:07

US3292149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 19:31:07

US3292149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	28 Sep 2020 19:31:07

US3292149

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 19:31:14

US3292149

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'l'	System	28 Sep 2020 19:31:14

US3292149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	05 Oct 2020 15:04:21

US3292149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '5 Oct 2020'	(b) (4) Kristy Trevino (b) (4)	05 Oct 2020 15:04:21

US3292149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	05 Oct 2020 15:04:21

US3292149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	05 Oct 2020 15:04:21

US3292149

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	05 Oct 2020 15:04:28

US3292149

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'l'	System	05 Oct 2020 15:04:28

US3292149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:26:40

US3292149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '8 Oct 2020'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:26:40

US3292149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[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 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Clinic (Clinic)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:26:40

US3292149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'VISIT3'	System	08 Oct 2020 13:26:40

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '8 Oct 2020'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '07:42'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '8 Oct 2020 07:42'	System	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '36.0' C	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Oral (Oral)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '49'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'bpm'	System	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '16'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'breaths/min'	System	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '153'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'mmHg'	System	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '89'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'mmHg'	System	08 Oct 2020 13:31:46

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58

US3292149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58

US3292149

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	
	System	08 Oct 2020 13:27:04
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	08 Oct 2020 13:26:50
User entered 'No (N)'	Kevin Martinez (b) (4)	08 Oct 2020 13:26:50
	(b) (4)	

US3292149

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kevin Martinez (b) (4)	08 Oct 2020 13:27:04
User entered '8 Oct 2020'	(b) (4)	
	Kevin Martinez (b) (4)	08 Oct 2020 13:26:50
	(b) (4)	

US3292149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:33:07

US3292149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '8 Oct 2020'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:33:07

US3292149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '07:54'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:33:07

US3292149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered '8 Oct 2020 07:54'	System	08 Oct 2020 13:33:07

US3292149

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:27:10

US3292149

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'I'	System	08 Oct 2020 13:27:10

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 64'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-10-15T13:53:48', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '70fa4a77-b5dd-44df-a480-fc0ab4930c7e'	System	15 Oct 2020 18:54:07
User entered 'No (N)'	System	15 Oct 2020 18:54:07

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Have you been exposed to someone with 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)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-10-15T13:53:55', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '70fa4a77-b5dd-44df-a480-fc0ab4930c7e'	System	15 Oct 2020 18:54:07
User entered 'No (N)'	System	15 Oct 2020 18:54:07

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-10-15T13:54:03', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '70fa4a77-b5dd-44df-a480-fc0ab4930c7e'	System	15 Oct 2020 18:54:07
User entered '15 Oct 2020 13:54:03'	System	15 Oct 2020 18:54:07

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 71'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-10-20T08:15:11', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b5b930cc-3fbb-47ec-913f-03167bfea2c8'	System	20 Oct 2020 13:16:44
User entered 'No (N)'	System	20 Oct 2020 13:16:44

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Have you been exposed to someone with 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)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-10-20T08:15:18', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b5b930cc-3fbb-47ec-913f-03167bfea2c8'	System	20 Oct 2020 13:16:44
User entered 'No (N)'	System	20 Oct 2020 13:16:44

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-10-20T08:15:29', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b5b930cc-3fbb-47ec-913f-03167bfea2c8'	System	20 Oct 2020 13:16:44
User entered '20 Oct 2020 08:15:29'	System	20 Oct 2020 13:16:44

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 78'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-10-27T08:38:49', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c210160a-4129-4e54-8053-6a77d6600718'	System	27 Oct 2020 13:39:04
User entered 'No (N)'	System	27 Oct 2020 13:39:04

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-10-27T08:38:56', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c210160a-4129-4e54-8053-6a77d6600718'	System	27 Oct 2020 13:39:04
User entered 'No (N)'	System	27 Oct 2020 13:39:04

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-10-27T08:39:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'c210160a-4129-4e54-8053-6a77d6600718' User entered '27 Oct 2020 08:39:00'	System	27 Oct 2020 13:39:04
	System	27 Oct 2020 13:39:04

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 92'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-11-10T08:39:19', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43159c79-3c37-4900-bc3d-e25417d1f54d'	System	10 Nov 2020 14:39:37
User entered 'No (N)'	System	10 Nov 2020 14:39:37

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Have you been exposed to someone with 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)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-11-10T08:39:28', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43159c79-3c37-4900-bc3d-e25417d1f54d'	System	10 Nov 2020 14:39:37
User entered 'No (N)'	System	10 Nov 2020 14:39:37

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-11-10T08:39:33', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '43159c79-3c37-4900-bc3d-e25417d1f54d'	System	10 Nov 2020 14:39:37
User entered '10 Nov 2020 08:39:33'	System	10 Nov 2020 14:39:37

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
Data entry locked.	System	13 Aug 2020 17:33:17
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22
Data entry locked.	System	13 Aug 2020 17:33:17
User entered 'Day 99'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Have you been exposed to someone with 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)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.		19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.		19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.		19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22
Data entry locked.	System	13 Aug 2020 17:33:17
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 17:33:17

US3292149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:54:26
DataPoint activated with code reason code Data required.		22 Nov 2020 16:36:49
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:05:22
Data entry locked.	System	13 Aug 2020 17:33:17
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 17:33:17

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2020-11-21T15:24:37', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ebb146fd-a2b7-4214-abb4-75227d7aa257'	System	21 Nov 2020 21:24:50
User entered 'No (N)'	System	21 Nov 2020 21:24:50

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2020-11-21T15:24:43', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ebb146fd-a2b7-4214-abb4-75227d7aa257'	System	21 Nov 2020 21:24:50
User entered 'No (N)'	System	21 Nov 2020 21:24:50

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-11-21T15:24:47', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ebb146fd-a2b7-4214-abb4-75227d7aa257'	System	21 Nov 2020 21:24:50
User entered '21 Nov 2020 15:24:47'	System	21 Nov 2020 21:24:50

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2020-11-28T07:05:55', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '04608ae6-f35d-4fcd-8d1c-8465b5ae98ab'	System	28 Nov 2020 13:06:08
User entered 'No (N)'	System	28 Nov 2020 13:06:08

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2020-11-28T07:06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '04608ae6-f35d-4fcd-8d1c-8465b5ae98ab'	System	28 Nov 2020 13:06:08
User entered 'No (N)'	System	28 Nov 2020 13:06:08

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-11-28T07:06:04', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '04608ae6-f35d-4fcd-8d1c-8465b5ae98ab' User entered '28 Nov 2020 07:06:04'	System	28 Nov 2020 13:06:08
	System	28 Nov 2020 13:06:08

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2020-12-05T18:43:31', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ef249ad8-13d7-4812-8097-15679ff38538'	System	06 Dec 2020 00:43:47
User entered 'No (N)'	System	06 Dec 2020 00:43:47

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2020-12-05T18:43:37', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ef249ad8-13d7-4812-8097-15679ff38538'	System	06 Dec 2020 00:43:47
User entered 'No (N)'	System	06 Dec 2020 00:43:47

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-12-05T18:43:42', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'ef249ad8-13d7-4812-8097-15679ff38538' User entered '05 Dec 2020 18:43:42'	System	06 Dec 2020 00:43:47
	System	06 Dec 2020 00:43:47

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2020-12-12T07:51:15', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fdbb1122-d73d-42e3-8890-de9891fdad01'	System	12 Dec 2020 13:51:29
User entered 'No (N)'	System	12 Dec 2020 13:51:29

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2020-12-12T07:51:22', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fdbb1122-d73d-42e3-8890-de9891fdad01'	System	12 Dec 2020 13:51:29
User entered 'No (N)'	System	12 Dec 2020 13:51:29

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-12-12T07:51:26', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'fdbb1122-d73d-42e3-8890-de9891fdad01'	System	12 Dec 2020 13:51:29
User entered '12 Dec 2020 07:51:26'	System	12 Dec 2020 13:51:29

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2020-12-19T10:24:25', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b255e555-b2f3-4932-8d45-17b0b085fd25'	System	19 Dec 2020 16:24:46
User entered 'No (N)'	System	19 Dec 2020 16:24:46

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2020-12-19T10:24:33', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b255e555-b2f3-4932-8d45-17b0b085fd25'	System	19 Dec 2020 16:24:46
User entered 'No (N)'	System	19 Dec 2020 16:24:46

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-12-19T10:24:42', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b255e555-b2f3-4932-8d45-17b0b085fd25' User entered '19 Dec 2020 10:24:42'	System	19 Dec 2020 16:24:46
	System	19 Dec 2020 16:24:46

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2020-12-26T08:58:28', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '71be42fa-1efb-474b-9a87-f2bf3463a43d'	System	26 Dec 2020 14:58:46
User entered 'No (N)'	System	26 Dec 2020 14:58:46

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2020-12-26T08:58:34', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '71be42fa-1efb-474b-9a87-f2bf3463a43d'	System	26 Dec 2020 14:58:46
User entered 'No (N)'	System	26 Dec 2020 14:58:46

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2020-12-26T08:58:44', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '71be42fa-1efb-474b-9a87-f2bf3463a43d' User entered '26 Dec 2020 08:58:44'	System	26 Dec 2020 14:58:46
	System	26 Dec 2020 14:58:46

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-01-02T08:30:27', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd5ef3bab-58b9-4811-8fe6-9b7c46275fcf'	System	02 Jan 2021 14:31:04
User entered 'Yes (Y)'	System	02 Jan 2021 14:31:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-01-02T08:30:36', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd5ef3bab-58b9-4811-8fe6-9b7c46275fcf'	System	02 Jan 2021 14:31:04
User entered 'No (N)'	System	02 Jan 2021 14:31:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-01-02T08:30:42', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd5ef3bab-58b9-4811-8fe6-9b7c46275fcf'	System	02 Jan 2021 14:31:04
User entered 'No (N)'	System	02 Jan 2021 14:31:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-01-02T08:30:53', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd5ef3bab-58b9-4811-8fe6-9b7c46275fcf'	System	02 Jan 2021 14:31:04
User entered 'No (N)'	System	02 Jan 2021 14:31:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-01-02T08:30:59', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'd5ef3bab-58b9-4811-8fe6-9b7c46275fcf'	System	02 Jan 2021 14:31:04
User entered '02 Jan 2021 08:30:59'	System	02 Jan 2021 14:31:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-01-09T07:02:26', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9ef9bc3a-2f67-43db-a5db-3f28514fa567'	System	09 Jan 2021 13:02:39
User entered 'No (N)'	System	09 Jan 2021 13:02:39

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-01-09T07:02:32', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9ef9bc3a-2f67-43db-a5db-3f28514fa567'	System	09 Jan 2021 13:02:39
User entered 'No (N)'	System	09 Jan 2021 13:02:39

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-01-09T07:02:36', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '9ef9bc3a-2f67-43db-a5db-3f28514fa567' User entered '09 Jan 2021 07:02:36'	System	09 Jan 2021 13:02:39
	System	09 Jan 2021 13:02:39

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-01-16T09:11:01', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '03cae1fe-e015-48a8-80d2-b58af200fad7'	System	16 Jan 2021 15:11:16
User entered 'No (N)'	System	16 Jan 2021 15:11:16

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-01-16T09:11:06', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '03cae1fe-e015-48a8-80d2-b58af200fad7'	System	16 Jan 2021 15:11:16
User entered 'No (N)'	System	16 Jan 2021 15:11:16

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-01-16T09:11:10', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '03cae1fe-e015-48a8-80d2-b58af200fad7' User entered '16 Jan 2021 09:11:10'	System	16 Jan 2021 15:11:16
	System	16 Jan 2021 15:11:16

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-01-23T07:49:52', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '77a124a8-961a-4c4f-897f-831bdb9eccc7'	System	23 Jan 2021 13:50:04
User entered 'No (N)'	System	23 Jan 2021 13:50:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-01-23T07:49:56', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '77a124a8-961a-4c4f-897f-831bdb9eccc7'	System	23 Jan 2021 13:50:04
User entered 'No (N)'	System	23 Jan 2021 13:50:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-01-23T07:50:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '77a124a8-961a-4c4f-897f-831bdb9eccc7'	System	23 Jan 2021 13:50:04
User entered '23 Jan 2021 07:50:00'	System	23 Jan 2021 13:50:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-01-30T18:10:05', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b926a967-841c-42dd-b114-9d6f53fd55f0'	System	31 Jan 2021 00:10:20
User entered 'No (N)'	System	31 Jan 2021 00:10:20

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-01-30T18:10:11', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b926a967-841c-42dd-b114-9d6f53fd55f0'	System	31 Jan 2021 00:10:20
User entered 'No (N)'	System	31 Jan 2021 00:10:20

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-01-30T18:10:15', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'b926a967-841c-42dd-b114-9d6f53fd55f0'	System	31 Jan 2021 00:10:20
User entered '30 Jan 2021 18:10:15'	System	31 Jan 2021 00:10:20

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-02-07T11:58:20', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '11570c69-f018-4a4f-8aaf-5300037e13b1'	System	07 Feb 2021 17:59:38
User entered 'Yes (Y)'	System	07 Feb 2021 17:59:38

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-02-07T11:58:24', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '11570c69-f018-4a4f-8aaf-5300037e13b1'	System	07 Feb 2021 17:59:38
User entered 'No (N)'	System	07 Feb 2021 17:59:38

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-02-07T11:58:29', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '11570c69-f018-4a4f-8aaf-5300037e13b1'	System	07 Feb 2021 17:59:38
User entered 'No (N)'	System	07 Feb 2021 17:59:38

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-02-07T11:58:41', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '11570c69-f018-4a4f-8aaf-5300037e13b1'	System	07 Feb 2021 17:59:38
User entered 'Yes (Y)'	System	07 Feb 2021 17:59:38

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Please 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 (1dabcc448832dabc)', Time: '2021-02-07T11:59:13', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '11570c69-f018-4a4f-8aaf-5300037e13b1'	System	07 Feb 2021 17:59:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Feb 2021 17:59:38

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-02-07T11:59:29', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '11570c69-f018-4a4f-8aaf-5300037e13b1' User entered '07 Feb 2021 11:59:29'	System	07 Feb 2021 17:59:38
	System	07 Feb 2021 17:59:38

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-02-13T07:44:25', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'cd5c9bbc-4969-4b31-bf0e-d8cdfbfdeb72'	System	13 Feb 2021 13:44:38
User entered 'No (N)'	System	13 Feb 2021 13:44:38

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-02-13T07:44:30', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'cd5c9bbc-4969-4b31-bf0e-d8cdfbfdeb72'	System	13 Feb 2021 13:44:38
User entered 'No (N)'	System	13 Feb 2021 13:44:38

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-02-13T07:44:34', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'cd5c9bbc-4969-4b31-bf0e-d8cdfbfdeb72'	System	13 Feb 2021 13:44:38
User entered '13 Feb 2021 07:44:34'	System	13 Feb 2021 13:44:38

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-02-20T07:22:20', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '4843efbf-09e8-4793-90d8-0f8e3f164ffd'	System	20 Feb 2021 13:22:31
User entered 'No (N)'	System	20 Feb 2021 13:22:31

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-02-20T07:22:24', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '4843efbf-09e8-4793-90d8-0f8e3f164ffd'	System	20 Feb 2021 13:22:31
User entered 'No (N)'	System	20 Feb 2021 13:22:31

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-02-20T07:22:28', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '4843efbf-09e8-4793-90d8-0f8e3f164ffd' User entered '20 Feb 2021 07:22:28'	System	20 Feb 2021 13:22:31
	System	20 Feb 2021 13:22:31

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-02-27T07:15:12-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'afe382de-10c2-49ad-a6ad-8a86482989b2' User entered 'No (N)'	System	27 Feb 2021 13:15:23
	System	27 Feb 2021 13:15:23

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-02-27T07:15:15-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'afe382de-10c2-49ad-a6ad-8a86482989b2'	System	27 Feb 2021 13:15:23
User entered 'No (N)'	System	27 Feb 2021 13:15:23

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-02-27T07:15:19-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'afe382de-10c2-49ad-a6ad-8a86482989b2'	System	27 Feb 2021 13:15:23
User entered '27 Feb 2021 07:15:19'	System	27 Feb 2021 13:15:23

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-03-06T07:12:28-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '265f1c99-cac5-4e71-8ff8-fe087ce08951' User entered 'No (N)'	System	06 Mar 2021 13:12:45

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-03-06T07:12:37-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '265f1c99-cac5-4e71-8ff8-fe087ce08951'	System	06 Mar 2021 13:12:45
User entered 'No (N)'	System	06 Mar 2021 13:12:45

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-03-06T07:12:41-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '265f1c99-cac5-4e71-8ff8-fe087ce08951' User entered '06 Mar 2021 07:12:41'	System	06 Mar 2021 13:12:45
	System	06 Mar 2021 13:12:45

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-03-13T09:26:32-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'cf624967-15a3-4872-bcaf-994dbbdc741'	System	13 Mar 2021 15:26:44
User entered 'No (N)'	System	13 Mar 2021 15:26:44

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-03-13T09:26:37-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'cf624967-15a3-4872-bcaf-994dbbdc741'	System	13 Mar 2021 15:26:44
User entered 'No (N)'	System	13 Mar 2021 15:26:44

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-03-13T09:26:41-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'cf624967-15a3-4872-bcaf-994dbbdc741'	System	13 Mar 2021 15:26:44
User entered '13 Mar 2021 09:26:41'	System	13 Mar 2021 15:26:44

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-03-20T14:59:30-07:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '03d82fbc-5edc-4084-b121-b1b481e68622'	System	20 Mar 2021 21:59:41
User entered 'No (N)'	System	20 Mar 2021 21:59:41

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-03-20T14:59:34-07:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '03d82fbc-5edc-4084-b121-b1b481e68622'	System	20 Mar 2021 21:59:41
User entered 'No (N)'	System	20 Mar 2021 21:59:41

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-03-20T14:59:38-07:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '03d82fbc-5edc-4084-b121-b1b481e68622' User entered '20 Mar 2021 14:59:38'	System	20 Mar 2021 21:59:41
	System	20 Mar 2021 21:59:41

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-03-27T07:34:58-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '049e6093-a452-4237-bd54-02ff47df9ec3'	System	27 Mar 2021 12:35:16
User entered 'No (N)'	System	27 Mar 2021 12:35:16

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-03-27T07:35:05-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '049e6093-a452-4237-bd54-02ff47df9ec3'	System	27 Mar 2021 12:35:16
User entered 'No (N)'	System	27 Mar 2021 12:35:16

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-03-27T07:35:09-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '049e6093-a452-4237-bd54-02ff47df9ec3' User entered '27 Mar 2021 07:35:09'	System	27 Mar 2021 12:35:16
	System	27 Mar 2021 12:35:16

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-04-03T07:40:44-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '0b5e4aff-0e63-420f-88eb-fb9f04536553'	System	03 Apr 2021 12:40:56
User entered 'No (N)'	System	03 Apr 2021 12:40:56

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-04-03T07:40:48-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '0b5e4aff-0e63-420f-88eb-fb9f04536553'	System	03 Apr 2021 12:40:56
User entered 'No (N)'	System	03 Apr 2021 12:40:56

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-04-03T07:40:52-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '0b5e4aff-0e63-420f-88eb-fb9f04536553'	System	03 Apr 2021 12:40:56
User entered '03 Apr 2021 07:40:52'	System	03 Apr 2021 12:40:56

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-04-10T07:31:28-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '5b0c7024-97f0-48be-94da-cc8ae40e4126'	System	10 Apr 2021 12:31:44
User entered 'No (N)'	System	10 Apr 2021 12:31:44

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-04-10T07:31:36-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '5b0c7024-97f0-48be-94da-cc8ae40e4126'	System	10 Apr 2021 12:31:44
User entered 'No (N)'	System	10 Apr 2021 12:31:44

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-04-10T07:31:39-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '5b0c7024-97f0-48be-94da-cc8ae40e4126'	System	10 Apr 2021 12:31:44
User entered '10 Apr 2021 07:31:39'	System	10 Apr 2021 12:31:44

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-04-17T08:23:41-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '7a3c0f98-51c2-486a-88db-44983728e225'	System	17 Apr 2021 13:23:53
User entered 'No (N)'	System	17 Apr 2021 13:23:53

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-04-17T08:23:46-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '7a3c0f98-51c2-486a-88db-44983728e225'	System	17 Apr 2021 13:23:53
User entered 'No (N)'	System	17 Apr 2021 13:23:53

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-04-17T08:23:50-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '7a3c0f98-51c2-486a-88db-44983728e225'	System	17 Apr 2021 13:23:53
User entered '17 Apr 2021 08:23:50'	System	17 Apr 2021 13:23:53

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-04-26T08:52:46-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '5700f914-4d0d-4788-8f20-89c3876fda8e' User entered 'No (N)'	System	26 Apr 2021 13:53:04
	System	26 Apr 2021 13:53:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-04-26T08:52:51-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '5700f914-4d0d-4788-8f20-89c3876fda8e' User entered 'No (N)'	System	26 Apr 2021 13:53:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-04-26T08:52:54-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '5700f914-4d0d-4788-8f20-89c3876fda8e' User entered '26 Apr 2021 08:52:54'	System	26 Apr 2021 13:53:04
	System	26 Apr 2021 13:53:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[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 (1dabcc448832dabc)', Time: '2021-05-01T08:26:47-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '167cbcd1-79b9-4bea-bcca-93f9de8ef1e1' User entered 'No (N)'	System	01 May 2021 13:27:04
	System	01 May 2021 13:27:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Have you been exposed to someone with 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 (1dabcc448832dabc)', Time: '2021-05-01T08:26:53-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '167cbcd1-79b9-4bea-bcca-93f9de8ef1e1'	System	01 May 2021 13:27:04
User entered 'No (N)'	System	01 May 2021 13:27:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-05-01T08:26:57-05:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: '167cbcd1-79b9-4bea-bcca-93f9de8ef1e1' User entered '01 May 2021 08:26:57'	System	01 May 2021 13:27:04
	System	01 May 2021 13:27:04

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:05:22

US3292149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:22
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:05:22

US3292149

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:24:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:47:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-02-27T07:15:30-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f3a4e6db-b713-4a0f-9dbf-7fab37219b49'	System	27 Feb 2021 13:15:37
User entered 'No (N)'	System	27 Feb 2021 13:15:37

US3292149

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:24:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:47:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1dabcc448832dabc)', Time: '2021-02-27T07:15:34-06:00', User OID: 'PatientReportedOutcome (US3292149)', ODM File OID: 'f3a4e6db-b713-4a0f-9dbf-7fab37219b49' User entered '27 Feb 2021 07:15:34'	System	27 Feb 2021 13:15:37
	System	27 Feb 2021 13:15:37

US3292149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Nov 2020 19:46:40

US3292149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '10 Nov 2020'	(b) (4) Gerardo Pena (b) (4)	12 Nov 2020 19:46:40

US3292149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	12 Nov 2020 19:46:40

US3292149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Nov 2020 19:46:40

US3292149

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Nov 2020 19:46:46

US3292149

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:54:58
User entered 'l'	System	12 Nov 2020 19:46:46

US3292149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	14 Dec 2020 16:41:39

US3292149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '11 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	14 Dec 2020 16:41:39

US3292149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	14 Dec 2020 16:41:39

US3292149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) Gerardo Pena (b) (4)	14 Dec 2020 16:41:39

US3292149

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	14 Dec 2020 16:44:24

US3292149

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User entered 'l'	System	14 Dec 2020 16:44:24

US3292149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 17:40:21

US3292149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '10 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 17:40:21

US3292149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 17:40:21

US3292149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 17:40:21

US3292149

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 17:40:32

US3292149

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User entered 'l'	System	11 Jan 2021 17:40:32

US3292149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 19:48:00

US3292149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '9 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 19:48:00

US3292149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Feb 2021 19:48:00

US3292149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 19:48:00

US3292149

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 19:48:05

US3292149

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:04
User entered 'l'	System	10 Feb 2021 19:48:05

US3292149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 19:35:40

US3292149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 19:35:40

US3292149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[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 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Mar 2021 19:35:40

US3292149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'VISIT4'	System	15 Mar 2021 19:35:40

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered empty.	System	30 Mar 2021 18:27:10

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23

US3292149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23

US3292149

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:36:07

US3292149

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:29
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:36:07

US3292149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 19:36:19

US3292149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 19:36:19

US3292149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered '08:54'	(b) (4), (b) (6)	15 Mar 2021 19:36:19

US3292149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered '15 Mar 2021 08:54'	System	15 Mar 2021 19:36:19

US3292149

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 19:36:23

US3292149

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:23
User entered 'I'	System	15 Mar 2021 19:36:23

US3292149

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:04:32

US3292149

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:04:32

US3292149

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:04:32

US3292149

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:04:32

US3292149

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:04:36

US3292149

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 13:04:36

US3292149

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

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:35:56

US3292149

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

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 20:35:56

US3292149

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

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Jan 2021 20:35:56

US3292149

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

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 20:35:56

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 20:37:27

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:50:41

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:37:27

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
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 04:50:41

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 20:37:27

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	13 Jan 2021 20:37:27

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 01:58:55
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	13 Jan 2021 20:37:27

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 01:58:55
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	13 Jan 2021 20:37:27

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:37:27

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'I'	System	13 Jan 2021 20:37:27

US3292149

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'I'	System	13 Jan 2021 20:37:27

US3292149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered empty.	System	13 Jan 2021 20:42:19
DataPoint set to visible.	System	13 Jan 2021 20:37:27

US3292149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered empty.	System	13 Jan 2021 20:42:19
DataPoint set to visible.	System	13 Jan 2021 20:37:27

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '11:45'	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered '12 Jan 2021 11:45'	System	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '36.4' C	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '50'	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'bpm'	System	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12'	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'breaths/min'	System	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '167'	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'mmHg'	System	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Jan 2021 20:42:37
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	13 Jan 2021 20:42:37
User entered '83' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:42:37
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Jan 2021 20:42:19
User entered '53'	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'mmHg'	System	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Jan 2021 20:42:19

US3292149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered empty.	System	13 Jan 2021 20:42:19
DataPoint set to visible.	System	13 Jan 2021 20:37:27

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '13:45'	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered '12 Jan 2021 13:45'	System	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '36.2' C	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '53'	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'bpm'	System	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '16'	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'breaths/min'	System	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '180'	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'mmHg'	System	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '93'	(b) (4), (b) (6)	13 Jan 2021 20:44:30

US3292149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'mmHg'	System	13 Jan 2021 20:44:30

US3292149

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:44:42

US3292149

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 20:44:42

US3292149

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

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:45:34

US3292149

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

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:45:34

US3292149

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

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

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)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:45:34

US3292149

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

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'mRNA-1273'	System	13 Jan 2021 20:45:34
DataPoint set to visible.	System	13 Jan 2021 20:37:27

US3292149

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

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 20:45:34

US3292149

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

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '13:13'	(b) (4), (b) (6)	13 Jan 2021 20:45:34

US3292149

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

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered '12 Jan 2021 13:13'	System	13 Jan 2021 20:45:34

US3292149

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

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Jan 2021 20:45:34

US3292149

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

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'ONCE'	System	13 Jan 2021 20:45:34

US3292149

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

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 20:45:34

US3292149

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:38:12

US3292149

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 20:38:12

US3292149

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12:00'	(b) (4), (b) (6)	13 Jan 2021 20:38:12

US3292149

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered '12 Jan 2021 12:00'	System	13 Jan 2021 20:38:12

US3292149

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:38:29

US3292149

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 20:38:29

US3292149

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12:25'	(b) (4), (b) (6)	13 Jan 2021 20:38:29

US3292149

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:38

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered '12 Jan 2021 12:25'	System	13 Jan 2021 20:38:29

US3292149

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

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:40:21

US3292149

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

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'I'	System	13 Jan 2021 20:40:21

US3292149

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	22 Jan 2021 17:41:13

US3292149

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '19 Jan 2021'	(b) (4) Gerardo Pena (b) (4)	22 Jan 2021 17:41:13

US3292149

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	22 Jan 2021 17:41:13

US3292149

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Jan 2021 17:41:13

US3292149

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	22 Jan 2021 17:41:17

US3292149

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'l'	System	22 Jan 2021 17:41:17

US3292149

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'I'	System	22 Jan 2021 17:41:17
DataPoint set to visible.	System	22 Jan 2021 17:41:17

US3292149

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:20:37

US3292149

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:20:37

US3292149

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Feb 2021 21:20:37

US3292149

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'OLD29'	System	09 Feb 2021 21:20:37

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '11:16'	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered '9 Feb 2021 11:16'	System	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '36.1' C	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '65'	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'bpm'	System	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12'	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'breaths/min'	System	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '130'	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'mmHg'	System	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '79'	(b) (4), (b) (6)	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'mmHg'	System	09 Feb 2021 21:21:22

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '12:41'	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered '9 Feb 2021 12:41'	System	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '36.3' C	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '62'	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'bpm'	System	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '16'	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'breaths/min'	System	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '141'	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'mmHg'	System	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '85'	(b) (4), (b) (6)	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'mmHg'	System	09 Feb 2021 21:24:09

US3292149

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:32:27

US3292149

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:32:27

US3292149

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:33:31

US3292149

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:33:31

US3292149

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

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)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:33:31

US3292149

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'mRNA-1273'	System	09 Feb 2021 21:33:31
DataPoint set to visible.	System	22 Jan 2021 17:41:17

US3292149

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:33:31

US3292149

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered '12:09'	(b) (4), (b) (6)	09 Feb 2021 21:33:31

US3292149

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered '9 Feb 2021 12:09'	System	09 Feb 2021 21:33:31

US3292149

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 09:20:46
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'Patient had pacemaker put in on left side. Right arm was used.' (Site from System).		01 Apr 2021 20:59:46
Amendment Manager: User opened query 'Treatment System Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).		17 Feb 2021 00:50:36
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	09 Feb 2021 21:33:31

US3292149

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'ONCE'	System	09 Feb 2021 21:33:31

US3292149

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 21:33:31

US3292149

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:33:38

US3292149

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'l'	System	09 Feb 2021 21:33:38

US3292149

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 14:29:02

US3292149

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 14:29:02

US3292149

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Feb 2021 14:29:02

US3292149

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 14:29:02

US3292149

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 14:29:07

US3292149

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'l'	System	17 Feb 2021 14:29:07

US3292149

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:48:32

US3292149

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered '9 Mar 2021'	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:48:32

US3292149

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered 'Clinic (Clinic)'	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:48:32

US3292149

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered 'OLD57'	System	10 Mar 2021 18:48:32

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered 'No (N)'	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered empty.	System	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered empty.	System	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered empty.	System	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered empty.	System	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered empty.	System	10 Mar 2021 18:49:13

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37

US3292149

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37

US3292149

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered 'No (N)'	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:39

US3292149

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:49:39

US3292149

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:50:11

US3292149

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered '9 Mar 2021'	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:50:11

US3292149

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:24:25
User entered '10:56'	(b) (4) Victoria Hernandez (b) (4)	10 Mar 2021 18:50:11

US3292149

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:38:37
User entered '9 Mar 2021 10:56'	System	10 Mar 2021 18:50:11

US3292149

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:24:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Antonio Gutierrez (b) (4)	08 Feb 2021 16:50:05
User entered 'No (N)'	Dawn Killian (b) (4)	03 Feb 2021 22:10:49
	(b) (4)	

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
Un-reviewed for Safety.	(b) (4)	29 Apr 2021 13:38:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:38:46
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:38:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:16
User entered 'USA-US072-2021-mRNA-1273-P301000013'	System	09 Feb 2021 13:27:13
User entered 'New'	(b) (4), (b) (6)	09 Feb 2021 13:27:13

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus node dysfunction, LLT: Sick sinus syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 17:09:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 17:09:35
Data point term sent to Coder	System	08 Feb 2021 17:08:36
User entered 'Sick Sinus Syndrome'	Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '1 Feb 2021'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '3 Feb 2021'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	29 Apr 2021 17:56:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'l'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '1 Feb 2021'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '3 Feb 2021'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '2'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Not Related (NOT RELATED)'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Not Related (NOT RELATED)'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'None (NONE)'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:37:11
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 21:01:07
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:52:26
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:10:40
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 13:10:10
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 04:39:12
User entered '1'	Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:53:10
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:09:53
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 04:39:01
User entered 'I'	Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:36:15
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:36:13
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:36:11
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4)	29 Apr 2021 13:38:09
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'This has been updated' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 21:00:15
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 12:59:41
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).	(b) (4), (b) (6)	27 Apr 2021 20:53:36
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 20:53:22
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'Pt has documented history with hypertension' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 20:08:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'sent labs to fax ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 22:03:21
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'COVID testing NOT done' (Site from Safety).		26 Apr 2021 21:52:40
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).		17 Feb 2021 14:33:15
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		17 Feb 2021 14:32:56
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		17 Feb 2021 14:32:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).		17 Feb 2021 14:32:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient contacted staff on Sunday, 07FEB2021 to report a recent hospitalization that took place 01FEB - 03FEB2021. Pt states he was sitting at home on 01FEB watching TV when he began to feel nauseous. He states he then passed out and his wife told him he was unresponsive for a few minutes. 911 was called and ambulance took him to ER. While in ER, patient states he was told his heart rhythm was abnormal. Tuesday morning, 02FEB, he was moved to ICU and scheduled to have pacemaker put in. Wednesday, 03FEB, patient was discharged in stable condition. Follow up with PCP and cardiologist scheduled. Medical records requested. Patient states he feels "like a million bucks" since being discharged.'	Antonio Gutierrez (b) (4)	08 Feb 2021 17:07:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Feb 2021 17:07:39

US3292149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:24:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Feb 2021 17:07:39

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:24:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:11:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 17:45:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:45:22
Data point term sent to Coder	System	14 Aug 2020 17:12:56
User entered 'Claritin'	(b) (4), (b) (6)	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Seasonal allergy'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 19:57:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:12:54
User entered 'un UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 17:12:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:12:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
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.	(b) (4) Coder Import (b) (4)	24 Sep 2020 15:23:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 15:23:52
Data point term sent to Coder Coding entries removed.	System Dawn Killian (b) (4)	24 Sep 2020 15:23:13 24 Sep 2020 15:22:47
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)	14 Aug 2020 17:14:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:14:17
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	14 Aug 2020 17:13:57 14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:02:18
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 15:22:53
User entered 'heart health' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	24 Sep 2020 15:22:47
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:22:26
User entered 'Supplement'	(b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '81'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	15 Aug 2020 19:57:42
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	14 Aug 2020 17:19:44
answered with 'Medication is ongoing, correct as entered.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:13:34
User entered 'un UNK 2010'	(b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 17:13:34

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
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)	14 Aug 2020 17:16:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:16:30
Data point term sent to Coder	System	14 Aug 2020 17:15:03
User entered 'Vitamin D3'	(b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '2000'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 19:57:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:14:20
User entered 'un UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 17:14:20

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 17:16:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:16:31
Data point term sent to Coder	System	14 Aug 2020 17:16:04
User entered 'Simvastatin'	(b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Hypercholesterolemia'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '40'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 19:57:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:15:11
User entered 'un UNK 2012'	(b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 17:15:11

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: BENAZEPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 17:18:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:18:16
Data point term sent to Coder	System	14 Aug 2020 17:17:05
User entered 'Benazepril'	(b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '20'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	(b) (4), (b) (6)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		15 Aug 2020 19:57:52
answered with 'Medication is ongoing, correct as entered.' (Site from System).		14 Aug 2020 17:19:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:16:35
User entered 'un UNK 2012'	(b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 21:17:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '2 Jan 2021' reason for change: Data Entry Error	(b) (4)	09 Feb 2021 21:17:35
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User entered 'l'	System	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User entered 'I'	System	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:33
User entered '804 (804)'	System	14 Aug 2020 17:16:35

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 17:18:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:18:18
Data point term sent to Coder	System	14 Aug 2020 17:18:09
User entered 'Tamsulosin'	(b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Benign prostatic hyperplasia'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0.4'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 19:57:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:17:54
User entered 'un UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 17:17:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL, PRODUCTSYNONYM: VIAGRA [SILDENAFIL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 17:20:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:20:20
Data point term sent to Coder	System	14 Aug 2020 17:19:11
User entered 'Viagra'	(b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Erectile dysfunction'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '50'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 19:57:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:18:43
User entered 'un UNK 2018'	(b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:18:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
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.	(b) (4) Coder Import (b) (4)	10 Nov 2020 20:56:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:56:41
Data point term sent to Coder	System	10 Nov 2020 18:03:54
User entered 'Flu shot'	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Influenza Vaccine'	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0.5'	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'once (ONCE)'	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '16 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User entered empty.	System	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User entered empty.	System	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:37
User entered empty.	System	10 Nov 2020 18:03:53

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 10:03:46
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' answered with 'AE was updated' (Site from DM).		28 Apr 2021 21:18:33
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).		05 Apr 2021 04:46:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: BENAZEPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Feb 2021 21:19:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 21:19:37
Data point term sent to Coder	System	09 Feb 2021 21:19:07
User entered 'benazepril'	(b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '30'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '3 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Feb 2021 21:18:31

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 10:07:06
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'AE has been recorded. (Site from DM).		28 Apr 2021 21:12:53
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).		05 Apr 2021 04:47:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NIFEDIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Feb 2021 21:21:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 21:21:38
Data point term sent to Coder	System	09 Feb 2021 21:21:09
User entered 'nifedipine'	(b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '60'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '3 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:05:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 13:05:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:05:29
User entered '5 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 13:05:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Feb 2021 21:20:18

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Apr 2021 13:08:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:08:52
Data point term sent to Coder	System	14 Apr 2021 13:07:08
User entered 'cardedilol'	(b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '3.125'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Apr 2021 13:06:51

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: OTHER CARDIAC STIMULANTS, PRODUCT: ATROPINE SULFATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Apr 2021 03:59:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 03:59:26
Data point term sent to Coder	System	28 Apr 2021 21:04:01
User entered 'Atropine Sulfate'	(b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Sick Sinus Syndrome'	(b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '10'	(b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '02 Feb 2021'	(b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User entered 'l'	System	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User entered 'l'	System	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:41
User entered '804 (804)'	System	28 Apr 2021 21:03:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: ISOPRENALINE HYDROCHLORIDE, PRODUCTSYNONYM: ISUPREL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Apr 2021 04:02:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 04:02:54
Data point term sent to Coder	System	28 Apr 2021 21:39:46
User entered 'Isuprel'	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'sick sinus syndrome'	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '5'	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'mL (mL)'	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User entered empty.	System	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User entered empty.	System	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:35
User entered empty.	System	28 Apr 2021 21:38:54

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: ENALAPRIL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Apr 2021 04:00:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 04:00:52
Data point term sent to Coder	System	28 Apr 2021 21:40:47
User entered 'Enalaprilet'	(b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'sick sinus syndrome'	(b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '1.25'	(b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User entered 'I'	System	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User entered 'I'	System	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:44
User entered '804 (804)'	System	28 Apr 2021 21:40:46

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Apr 2021 21:43:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 21:43:27
Data point term sent to Coder	System	28 Apr 2021 21:41:48
User entered 'Tylenol'	(b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Sick sinus syndrome'	(b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '325'	(b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User entered empty.	System	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User entered empty.	System	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:49
User entered empty.	System	28 Apr 2021 21:41:43

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Apr 2021 03:48:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 03:48:34
Data point term sent to Coder	System	28 Apr 2021 21:43:49
User entered 'Sodium Chloride'	(b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Sick sinus syndrome'	(b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '1000'	(b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User entered 'l'	System	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User entered 'I'	System	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:52
User entered '804 (804)'	System	28 Apr 2021 21:42:59

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 03:46:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 03:46:29
Data point term sent to Coder	System	28 Apr 2021 21:44:50
User entered 'Zofran'	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Sick Sinus Syndrome'	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '4'	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 21:44:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 21:44:20
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 21:44:13
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User entered empty.	System	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User entered empty.	System	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:00
User entered empty.	System	28 Apr 2021 21:44:13

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 04:00:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 04:00:52
Data point term sent to Coder	System	28 Apr 2021 21:45:53
User entered 'Fentanyl'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Sick Sinus Syndrome'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '25'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Other (OTHER)'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Mcg'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '5 times'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '02 Feb 2021'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User entered empty.	System	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User entered empty.	System	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:03
User entered empty.	System	28 Apr 2021 21:45:52

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Apr 2021 03:47:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 03:47:47
Data point term sent to Coder	System	28 Apr 2021 21:48:05
User entered 'Versed'	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Sick Sinus Syndrome'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'l'	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '5 times'	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User entered empty.	System	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User entered empty.	System	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:06
User entered empty.	System	28 Apr 2021 21:48:03

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN SODIUM, PRODUCTSYNONYM: KEFZOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Apr 2021 04:04:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 04:04:11
Data point term sent to Coder	System	28 Apr 2021 21:52:14
User entered 'Kefzol 1 GM'	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'Sick Sinus Syndrome'	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '1000'	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 21:52:07
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 21:52:07
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 21:51:14
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 21:52:07
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 21:52:07
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 21:51:14
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '02 Feb 2021'	(b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User entered empty.	System	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User entered empty.	System	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:24:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:29
User entered empty.	System	28 Apr 2021 21:51:14

US3292149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:24:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 13:08:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 13:08:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'No (N)'	Dawn Killian (b) (4)	04 Feb 2021 16:27:52

US3292149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:24:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:08:46

US3292149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:24:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered 'PACE MAKER INSERTION' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 13:09:06
User entered 'pace maker insertio'	(b) (4), (b) (6)	14 Apr 2021 13:08:46

US3292149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:24:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:08:46

US3292149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:24:38

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:08:46

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'USA-US072-2021-MRNA-1273-P301000013'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Douglas'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Denham'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered '7940 Floyd Curl Drive'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'San Antonio'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered '78229'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'US'	(b) (4) System	09 Feb 2021 13:27:45

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 13:39:52
User entered '2'	System	15 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '1'	(b) (4) System	09 Feb 2021 13:27:45

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'USA-US072-2021-MRNA-1273-P301000013'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Douglas'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Denham'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered '7940 Floyd Curl Drive'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'San Antonio'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered '78229'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'US'	(b) (4) System	09 Feb 2021 13:27:45

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 13:39:52
User entered '2'	System	15 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '1'	(b) (4) System	09 Feb 2021 13:27:45

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:24:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '09/Feb/2021 13:27'	(b) (4) System	09 Feb 2021 13:27:45

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:24:38

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'I'	(b) (4), (b) (6)	09 Feb 2021 13:27:45

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'USA-US072-2021-MRNA-1273-P301000013'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Douglas'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Denham'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered '7940 Floyd Curl Drive'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'San Antonio'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered '78229'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'US'	(b) (4) System	09 Feb 2021 13:27:45

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 13:39:52
User entered '2'	System	15 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '1'	(b) (4) System	09 Feb 2021 13:27:45

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:24:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered '15/Apr/2021 11:10'	(b) (4) System	15 Apr 2021 15:10:50

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:24:38

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:18
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 15:10:50

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'USA-US072-2021-MRNA-1273-P301000013'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Yes (Y)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'No (N)'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Douglas'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'Denham'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered '7940 Floyd Curl Drive'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered 'San Antonio'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:27:39
User entered '78229'	System	09 Feb 2021 13:27:13

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered 'US'	(b) (4) System	09 Feb 2021 13:27:45

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 13:39:52
User entered '2'	System	15 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 18:55:25
User entered '1'	(b) (4) System	09 Feb 2021 13:27:45

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:24:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered '29/Apr/2021 09:39'	(b) (4) System	29 Apr 2021 13:39:52

US3292149

Folder: SAE USA-US072-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:24:38

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:38:25
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:34
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 13:39:52