

US3012131 (Prod: Benchmark Research-Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:46:53

All time stamps listed in this document are displayed in GMT

US3012131

Form: Participant Creation

Data signed: (b) (4) 26 Mar 2021 00:52:44

Generated On: 09 Jun 2021 14:46:53

[Participant ID](#)

US3012131

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

US3012131

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 20:26:50

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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) 12 Feb 2021 20:26:50

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 20:26:50

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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) 12 Feb 2021 20:26:50

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Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Condition	IMPLANTED NEUROSTIMULATOR, DUE TO REFLUX SYMPATHETIC DYSTROPHY, LEFT WRIST
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Condition	INSOMNIA
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 (10)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Condition	NERVE PAIN, DUE TO REFLUX SYMPATHETIC DYSTROPHY
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) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Condition	GENERAL MYALGIAS
Start date (dd MMM yyyy)	UN JUL 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)	JUL 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) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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)	14:36 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 14:36
Height (xxx.x)	65.0 in
Weight (xxx.x)	153.3 lb
BMI (xxx.x)	25.56380 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) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 20:26:50

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Date of assessment (*dd MMM yyyy*) 13 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 1997

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:26:50

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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

What was the participant's randomization number? 186033

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) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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)	14:36 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 14:36
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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)	17:21 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 17:21
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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) 16:27 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 16:27

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 AUG 2020
Collection time (00:00-23:59)	15:53 (24 HR)
Collection date and time (derived)	13 AUG 2020 15:53

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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	15:06	13 AUG 2020 15:06
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

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 14:46:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 17:27

PC Open Date & Time

13 AUG 2020 16:47

PC Close Date & Time

13 AUG 2020 19:17

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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 97.7 °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	14 AUG 2020 01:09
PC Open Date & Time	13 AUG 2020 20:12
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 20:06

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 19:06

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

16 AUG 2020 18:40

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

17 AUG 2020 18:43

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

97.7 °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

18 AUG 2020 18:24

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

19 AUG 2020 19:00

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 17:32

PC Open Date & Time

13 AUG 2020 16:47

PC Close Date & Time

13 AUG 2020 19:17

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

14 AUG 2020 01:09

PC Open Date & Time

13 AUG 2020 20:12

PC Close Date & Time

14 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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 20:07

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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 19:07

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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 18:40

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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 18:44

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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 18:25

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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 19:01

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 17:34
PC Open Date & Time	13 AUG 2020 16:47
PC Close Date & Time	13 AUG 2020 19:17

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 01:10
PC Open Date & Time	13 AUG 2020 20:12
PC Close Date & Time	14 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:08
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:08
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 18:42
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 18:45
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 18:26
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 19:02
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3012131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:26:29

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:26:29

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:26:30

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:26:29

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

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)	10 SEP 2020
Time of assessment (00:00-23:59)	09:51 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:51
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

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)	10 SEP 2020
Time of assessment (00:00-23:59)	12:21 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:21
Temperature (xxx.x)	97.9 F
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3012131

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3012131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

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) 10 SEP 2020

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

Treatment Date and Time (derived) 10 SEP 2020 11:11

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

US3012131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	10:34 (24 HR)
Collection date and time (derived)	10 SEP 2020 10:34

US3012131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:17	10 SEP 2020 10:17
Nasopharyngeal Swab 2	No		

US3012131

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:26:50

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

97.9 °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

10 SEP 2020 12:14

PC Open Date & Time

10 SEP 2020 11:31

PC Close Date & Time

10 SEP 2020 14:01

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	10 SEP 2020 19:26
PC Open Date & Time	10 SEP 2020 14:56
PC Close Date & Time	11 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

11 SEP 2020 18:03

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 18:18

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 03:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 18:33

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

97.9 °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

15 SEP 2020 18:49

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 18:34

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 12:15

PC Open Date & Time

10 SEP 2020 11:31

PC Close Date & Time

10 SEP 2020 14:01

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

10 SEP 2020 19:27

PC Open Date & Time

10 SEP 2020 14:56

PC Close Date & Time

11 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

11 SEP 2020 18:04

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

12 SEP 2020 18:18

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

14 SEP 2020 03:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

14 SEP 2020 18:33

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

15 SEP 2020 18:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

16 SEP 2020 18:34

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 12:16
PC Open Date & Time	10 SEP 2020 11:31
PC Close Date & Time	10 SEP 2020 14:01

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 19:28
PC Open Date & Time	10 SEP 2020 14:56
PC Close Date & Time	11 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:05
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:19
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 03:07
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:34
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 18:50
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:35
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3012131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:26:30

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:26:30

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:26:30

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:26:30

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:26:30

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:26:30

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:20 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 10:20
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

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.

US3012131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

10:39 (24 HR)

Collection date and time (derived)

14 OCT 2020 10:39

US3012131

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:26:51

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

23 OCT 2020 17:59:15

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 19:26:51

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 <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 NOV 2020 20:31:32
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 12:51:32

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 18:49:20

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 17:40:30

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	13 DEC 2020 12:34:45
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

20 DEC 2020 16:23:44

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

27 DEC 2020 09:10:10

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 08:42:14
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

10 JAN 2021 17:51:19

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

18 JAN 2021 12:38:40

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

24 JAN 2021 19:25:58

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 08:49:13

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 18:33:42
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 19:17:17
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 FEB 2021 03:21:53
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 16:09:26

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

08 MAR 2021 00:10:46

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

17 MAR 2021 13:13:30

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 17:23:58

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 11:02:31

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

05 APR 2021 07:58:45

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

11 APR 2021 19:03:28

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

19 APR 2021 16:23:43

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 11:50:45

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 18:19:23

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 299

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

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

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

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

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

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

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 488

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

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

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

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

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 495

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

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

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

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

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

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

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

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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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

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23 FEB 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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02 MAR 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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05 MAR 2022 00:01

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09 MAR 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

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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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3012131

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:46:53

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		08 MAR 2021 00:11:08

US3012131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:27:26

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:27:26

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 00:52:46

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 14:52:06

Generated On: 09 Jun 2021 14:46:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 MAR 2021
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 10:30
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 00:52:46

Generated On: 09 Jun 2021 14:46:53

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.

US3012131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 14:52:06

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 MAR 2021
Collection time (00:00-23:59)	10:39 (24 HR)
Collection date and time (derived)	10 MAR 2021 10:39

US3012131

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:52:46

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 14:52:06

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 14:52:06

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3012131

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

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"/>

US3012131

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:46:53

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3012131

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

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 JAN 2021
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

US3012131

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Date of updated informed consent (<i>dd MMM yyyy</i>)	8 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>)	8 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

US3012131

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Height	65 in
Weight	159.8 lb
BMI (xxx.x)	26.64771

US3012131

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Height	65 in
Weight	159.8 lb
BMI (xxx.x)	26.64771
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)	8 JAN 2021
Time of assessment (00:00-23:59)	14:38 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 14:38
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3012131

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Height	65 in
Weight	159.8 lb
BMI (xxx.x)	26.64771
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)	8 JAN 2021
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 16:45
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3012131

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

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 JAN 2021

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

US3012131

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

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

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) 8 JAN 2021

What was the treatment time? (00:00-23:59) 15:56 (24 HR)

Treatment Date and Time (derived) 8 JAN 2021 15:56

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

What was the frequency of the study treatment dosing? ONCE

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

US3012131

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00-23:59)

15:08 (24 HR)

Collection date and time (derived)

8 JAN 2021 15:08

US3012131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	14:56
Collection Date and Time (derived)	8 JAN 2021 14:56

US3012131

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

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:52:46

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:52:46

Generated On: 09 Jun 2021 14:46:53

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

US3012131

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

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)	05 FEB 2021
Time of assessment (00:00-23:59)	11:17 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 11:17
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

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)	05 FEB 2021
Time of assessment (00:00-23:59)	12:58 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 12:58
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3012131

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 FEB 2021

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

US3012131

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

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) 05 FEB 2021

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

Treatment Date and Time (derived) 05 FEB 2021 12:23

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

US3012131

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012131

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012131

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:30 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 10:30
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012131

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

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.

US3012131

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 MAR 2021
Collection time (00:00-23:59)	10:39 (24 HR)
Collection date and time (derived)	10 MAR 2021 10:39

US3012131

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 19:34:24

Generated On: 09 Jun 2021 14:46:53

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) 12 Mar 2021 19:34:24

Generated On: 09 Jun 2021 14:46:53

AEID	USA-US006-2020-MRNA-1273-P30 1000004
Adverse event	STROKE
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)	11 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	11 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	13 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 19:34:24

Generated On: 09 Jun 2021 14:46:53

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PT REPORTED SHE HAD A STROKE IN THE MID MORNING AND RUSHED TO THE ER. SHE WAS GIVEN AN INJECTION OF TENECTEPLASE AND OBSERVED UNTIL THE MORNING OF 13DEC2020

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 19:34:24

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

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

Yes ☒

No ☐

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

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication DOXEPIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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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EAB) (1725)

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US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	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"/>

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NERVE PAIN, DUE TO REFLUX
SYMPATHETIC DYSTROPHY

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 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 (3)

Data signed: (b) (4) 16 Apr 2021 15:22:15

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Name of Medication TIMOLOL MALEALE

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA, BILATERAL

Dose per administration 6.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication PROLIA

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

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

Q6M

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) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (5)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication EYLEA

Prophylaxis Yes ☐
No ☒

Indication MACULAR DEGENERATION,
BILATERAL

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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 Q6W

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 15:22:15

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	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 checked="" type="radio"/>
If route of administration is Other, specify	INTRAVITREAL	
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (6)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 50000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication CALCIUM CITRATE / D3

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 630

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) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication OCUVITE
(MULTIVITAMIN/MINERALS)

Prophylaxis Yes ☐
No ☒

Indication MACULAR DEGENERATION,
BILATERAL

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 15:22:15

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Name of Medication B-COMPLEX

Prophylaxis Yes ☐
No ☒

Indication CHRONIC FATIGUE

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 (9)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 15:22:15

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication GENERAL MYALGIAS

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 (10)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 15:22:15

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify SHOT

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) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	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)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 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 (12)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication TENECTEPLASE

Prophylaxis Yes ☐
No ☒

Indication STROKE

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	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)		11 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 DEC 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 (13)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication BABY ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	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)	13 DEC 2020	
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"/>

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication PEPCID (FAMOTIDINE)

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS AFTER EPISODE
OF CVA/STROKE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 DEC 2020
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"/>

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

Name of Medication CLYNDIMYCIN

Prophylaxis Yes ☐
No ☒

Indication TOOTH INFECTION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 15:22:15

Generated On: 09 Jun 2021 14:46:53

	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)	08 MAR 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3012131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US006-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 00:52:45

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US006-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	15/DEC/2020 11:27
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

Audit

US3012131 (Prod: Benchmark Research-Austin)

US3012131

Form: Participant Creation

Generated On: 09 Jun 2021 14:46:53

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 13:14:23
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'US3012131'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 19:09:13

US3012131

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:42

US3012131

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 19:09:14

US3012131

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Clinic (Clinic)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:42

US3012131

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'SCRN'	(b) (4), (b) (6) System	13 Aug 2020 21:02:42

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered (b) (6)1945'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 19:09:15

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '75'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'YEARS'	(b) (4), (b) (6) System	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '75'	(b) (4), (b) (6) System	13 Aug 2020 21:03:00

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Female (F)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'I'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:52

US3012131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '13 Aug 2020'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:03:00

US3012131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Aug 2020'	(b) (4), (b) (6) System	13 Aug 2020 21:03:00

US3012131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2020'	(b) (4), (b) (6) System	13 Aug 2020 21:03:00

US3012131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Amendment 2 (2)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:03:00

US3012131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:03:00

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:03:00

US3012131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:03:00

US3012131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:03:00

US3012131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 19:09:14

US3012131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'I'	(b) (4), (b) (6) System	13 Aug 2020 21:03:03

US3012131

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:03:03

US3012131

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:46:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM: Please complete the Medical History form' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 15:14:25
Query 'Per CDM: Please complete the Medical History form' answered with 'MEDICAL HISTORY FORM IS COMPLETED' (Site from DM).	Lamar Box (b) (4) (b) (4)	15 Sep 2020 22:09:58
User opened query 'Per CDM: Please complete the Medical History form' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Aug 2020 20:21:57
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:00:00

US3012131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
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: Penicillin allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 15:48:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:48:36
Data point term sent to Coder	System	31 Aug 2020 15:47:19
User entered 'allergy to penicillin'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:34

US3012131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN UNK 1988'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:34

US3012131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:34

US3012131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:34

US3012131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:34

US3012131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:34

US3012131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 1988'	(b) (4), (b) (6) System	31 Aug 2020 15:46:34

US3012131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '1988'	(b) (4), (b) (6) System	31 Aug 2020 15:46:34

US3012131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:46:34

US3012131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:46:34

US3012131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Hypoacusis, LLT: Hearing decreased - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 18:00:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:00:36
Data point term sent to Coder	System	31 Aug 2020 15:47:20
User entered 'decreased hearing, bilateral'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:55

US3012131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN UNK 2016'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:55

US3012131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:55

US3012131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:55

US3012131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:55

US3012131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:46:55

US3012131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 2016'	(b) (4), (b) (6) System	31 Aug 2020 15:46:55

US3012131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2016'	(b) (4), (b) (6) System	31 Aug 2020 15:46:55

US3012131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:46:55

US3012131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:46:55

US3012131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo positional, LLT: BPPV - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 15:48:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:48:36
Data point term sent to Coder	System	31 Aug 2020 15:47:20
User entered 'BPPV'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:20

US3012131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN UNK 2010'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:20

US3012131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:20

US3012131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:20

US3012131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:20

US3012131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:20

US3012131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 2010'	(b) (4), (b) (6) System	31 Aug 2020 15:47:20

US3012131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2010'	(b) (4), (b) (6) System	31 Aug 2020 15:47:20

US3012131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:47:20

US3012131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:47:20

US3012131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 15:49:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:49:41
Data point term sent to Coder	System	31 Aug 2020 15:48:23
User entered 'postmenopausal'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:36

US3012131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per DM CLR: Please review the start date of this Condition as it does not match with the details when the subject had her last menstruation. Please reconcile with Childbearing and Pregnancy Test eCRF and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	18 Sep 2020 13:15:20
Query 'Per DM CLR: Please review the start date of this Condition as it does not match with the details when the subject had her last menstruation. Please reconcile with Childbearing and Pregnancy Test eCRF and update as appropriate. Otherwise, clarify.' answered with 'DATA CORRECTED' (Site from DM).	Lamar Box (b) (4) (b) (4)	15 Sep 2020 22:13:46
User entered 'UN UNK 1997' reason for change: Data Entry Error	Lamar Box (b) (4) (b) (4)	15 Sep 2020 22:13:40
User opened query 'Per DM CLR: Please review the start date of this Condition as it does not match with the details when the subject had her last menstruation. Please reconcile with Childbearing and Pregnancy Test eCRF and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Sep 2020 06:04:00
User entered 'UN UNK 1998'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:36

US3012131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:36

US3012131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:36

US3012131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:36

US3012131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:47:36

US3012131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 1997'	(b) (4), (b) (6) System	15 Sep 2020 22:13:40
User entered 'Jan 1998'	System	31 Aug 2020 15:47:36

US3012131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '1997'	(b) (4), (b) (6) System	15 Sep 2020 22:13:40
User entered '1998'	System	31 Aug 2020 15:47:36

US3012131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:47:36

US3012131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:47:36

US3012131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 15:50:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:50:31
Data point term sent to Coder	System	31 Aug 2020 15:49:24
User entered 'osteoporosis'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:48:39

US3012131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN UNK 2010'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:48:39

US3012131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:48:39

US3012131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:48:39

US3012131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:48:39

US3012131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:48:39

US3012131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 2010'	(b) (4), (b) (6) System	31 Aug 2020 15:48:39

US3012131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2010'	(b) (4), (b) (6) System	31 Aug 2020 15:48:39

US3012131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:48:39

US3012131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:48:39

US3012131

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Complex regional pain syndrome, LLT: Reflex sympathetic dystrophy of the upper limb - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 09:36:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 09:36:55
Data point term sent to Coder	System	31 Aug 2020 15:51:30
User entered 'REFLUX SYMPATHETIC DYSTROPHY, left wrist' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:50:34
Data point term sent to Coder	System	31 Aug 2020 15:49:27
User entered 'reflux sympathetic dystrophy'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:49:20

US3012131

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN UNK 2010'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:49:20

US3012131

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:49:20

US3012131

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:49:20

US3012131

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:49:20

US3012131

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:49:20

US3012131

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 2010'	(b) (4), (b) (6) System	31 Aug 2020 15:49:20

US3012131

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2010'	(b) (4), (b) (6) System	31 Aug 2020 15:49:20

US3012131

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:49:20

US3012131

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:49:20

US3012131

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Nervous system therapeutic procedures NEC, PT: Neuroprosthesis implantation, LLT: Neurostimulator implantation - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	08 Sep 2020 20:04:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:04:51
Data point term sent to Coder	System	31 Aug 2020 15:50:30
User entered 'implanted neurostimulator, due to reflux sympathetic dystrophy, left wrist'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:50:25

US3012131

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Un UNK 2012'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:50:25

US3012131

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:50:25

US3012131

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:50:25

US3012131

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:50:25

US3012131

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:50:25

US3012131

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 2012'	(b) (4), (b) (6) System	31 Aug 2020 15:50:25

US3012131

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2012'	(b) (4), (b) (6) System	31 Aug 2020 15:50:25

US3012131

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:50:25

US3012131

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 15:50:25

US3012131

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Macular degeneration, LLT: Macular degeneration - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Sep 2020 19:39:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:39:39
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Macular degeneration, LLT: Degeneration macular - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:12:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:12:35
Data point term sent to Coder	System	31 Aug 2020 16:11:45
User entered 'macular degeneration, bilateral'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:33

US3012131

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN UNK 2010'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:33

US3012131

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:33

US3012131

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:33

US3012131

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:33

US3012131

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:33

US3012131

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 2010'	(b) (4), (b) (6) System	31 Aug 2020 16:11:33

US3012131

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2010'	(b) (4), (b) (6) System	31 Aug 2020 16:11:33

US3012131

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 16:11:33

US3012131

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 16:11:33

US3012131

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 16:12:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:12:35
Data point term sent to Coder	System	31 Aug 2020 16:11:45
User entered 'insomnia'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:43

US3012131

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN UNK 2015'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:43

US3012131

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:43

US3012131

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:43

US3012131

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:43

US3012131

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:11:43

US3012131

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 2015'	(b) (4), (b) (6) System	31 Aug 2020 16:11:43

US3012131

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2015'	(b) (4), (b) (6) System	31 Aug 2020 16:11:43

US3012131

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 16:11:43

US3012131

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 16:11:43

US3012131

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Complex regional pain syndrome, LLT: Reflex sympathetic dystrophy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Nov 2020 05:44:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 05:44:08
Data point term sent to Coder	System	31 Aug 2020 16:12:48
User entered 'nerve pain, due to reflux sympathetic dystrophy'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:19

US3012131

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN UNK 2015'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:19

US3012131

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:19

US3012131

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:19

US3012131

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:19

US3012131

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:19

US3012131

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 2015'	(b) (4), (b) (6) System	31 Aug 2020 16:12:19

US3012131

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2015'	(b) (4), (b) (6) System	31 Aug 2020 16:12:19

US3012131

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 16:12:19

US3012131

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 16:12:19

US3012131

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Chronic fatigue - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 16:13:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:13:38
Data point term sent to Coder	System	31 Aug 2020 16:12:48
User entered 'chronic fatigue'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:32

US3012131

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN UNK 2016'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:32

US3012131

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:32

US3012131

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:32

US3012131

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:32

US3012131

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:12:32

US3012131

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 2016'	(b) (4), (b) (6) System	31 Aug 2020 16:12:32

US3012131

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2016'	(b) (4), (b) (6) System	31 Aug 2020 16:12:32

US3012131

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 16:12:32

US3012131

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 16:12:32

US3012131

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma both eyes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	22 Sep 2020 00:13:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 00:13:51
Data point term sent to Coder	System	22 Sep 2020 00:13:22
User entered 'glaucoma, bilateral'	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:13:11

US3012131

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN UNK 2019'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:13:11

US3012131

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:13:11

US3012131

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:13:11

US3012131

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:13:11

US3012131

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:13:11

US3012131

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jan 2019'	(b) (4), (b) (6) System	22 Sep 2020 00:13:11

US3012131

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2019'	(b) (4), (b) (6) System	22 Sep 2020 00:13:11

US3012131

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	22 Sep 2020 00:13:11

US3012131

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	22 Sep 2020 00:13:11

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	22 Sep 2020 00:15:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 00:15:53
Data point term sent to Coder	System	22 Sep 2020 00:15:23
User entered 'general myalgias'	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:14:45

US3012131

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'UN Jul 2019'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:14:45

US3012131

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:14:45

US3012131

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:14:45

US3012131

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:14:45

US3012131

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:14:45

US3012131

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'Jul 2019'	(b) (4), (b) (6) System	22 Sep 2020 00:14:45

US3012131

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '2019'	(b) (4), (b) (6) System	22 Sep 2020 00:14:45

US3012131

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	22 Sep 2020 00:14:45

US3012131

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered empty.	(b) (4), (b) (6) System	22 Sep 2020 00:14:45

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '13 Aug 2020'	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:01:35
	(b) (4)	

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '14:36'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered '13 Aug 2020 14:36'	(b) (4), (b) (6) System	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '65.0' in	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:01:35
DataPoint set to visible.	(b) (4) System	13 Aug 2020 21:03:03

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '153.3' lb	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:01:35
DataPoint set to visible.	(b) (4) System	13 Aug 2020 21:03:03

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
Amendment Manager: User entered '25.56380'	(b) (4), (b) (6) System	16 Sep 2020 23:56:01
User entered '25.6'	System	13 Aug 2020 23:01:35
DataPoint set to visible.	System	13 Aug 2020 21:03:03

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'kg/m2'	(b) (4), (b) (6) System	13 Aug 2020 23:01:35
DataPoint set to visible.	System	13 Aug 2020 21:03:03

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded for TEMPERATURE and remove Route. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Sep 2020 18:32:18
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded for TEMPERATURE and remove Route. Please update accordingly.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 15:07:44
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 15:07:40
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded for TEMPERATURE and remove Route. Please update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Aug 2020 20:23:51
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Aug 2020 20:23:12
User opened query 'Per CDM: 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) (b) (4), (b) (6)	23 Aug 2020 20:22:43
User entered '98.7' F	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty; reason for change New Information	(b) (4) Jennifer Leyva (b) (4)	11 Sep 2020 15:07:40
User entered 'Oral (Oral)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	18 Aug 2020 11:43:18
Query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' answered with 'Entered' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 21:23:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 21:22:59
User opened query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Aug 2020 10:44:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Aug 2020 10:44:02
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:01:59
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 23:01:35
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'bpm'	(b) (4), (b) (6) System	17 Aug 2020 21:22:59
User entered empty.	System	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	18 Aug 2020 11:43:21
Query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' answered with 'Entered' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 21:23:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 21:22:59
User opened query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Aug 2020 10:44:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Aug 2020 10:44:05
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:00
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 23:01:35
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Aug 2020 21:22:59
User entered empty.	System	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	18 Aug 2020 11:43:24
Query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' answered with 'Entered' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 21:23:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 21:22:59
User opened query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Aug 2020 10:45:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Aug 2020 10:44:13
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:01
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 23:01:35
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:01:35

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 21:22:59
User entered empty.	System	13 Aug 2020 23:01:35

US3012131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	18 Aug 2020 11:43:27
Query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' answered with 'Entered' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 21:23:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 21:22:59
User opened query 'Per CDM: Response noted, kindly consider to enter "ND" in data field' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Aug 2020 10:45:10
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Aug 2020 10:44:24
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:02
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 23:01:35
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:01:35

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User entered 'mmHg'	(b) (4), (b) (6) System	17 Aug 2020 21:22:59
User entered empty.	System	13 Aug 2020 23:01:35

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	(b) (4), (b) (6) 26 Apr 2021 11:41:37

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	(b) (4), (b) (6) 26 Apr 2021 11:41:37

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:18

US3012131

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	11 Sep 2020 09:55:55
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 16:07:28
User entered '13 Aug 2020'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:18

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '13 Aug 2020'	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:02:57
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:02:57
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM, re-query: thank you for your response, however, the medical history form is blank. Please agree to update the medical history form.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	31 Aug 2020 21:09:21
Query 'Per CDM, re-query: thank you for your response, however, the medical history form is blank. Please agree to update the medical history form.' answered with 'Added/Entered' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:00:53
User opened query 'Per CDM, re-query: thank you for your response, however, the medical history form is blank. Please agree to update the medical history form.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	31 Aug 2020 12:26:52
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	31 Aug 2020 12:26:52
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'Per PI, postmenopausal status is reached once without menses for one year.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 13:47:42
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Aug 2020 11:37:10
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:57

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:57

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:57

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:57

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM: In the Medical History form the date for "Post-Menopausal" is given as "UN UNK 1998". Please review the date of surgery field in this form and update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 05:21:55
Query 'Per CDM: In the Medical History form the date for "Post-Menopausal" is given as "UN UNK 1998". Please review the date of surgery field in this form and update accordingly. Thank you.' answered with 'Postmenopausal status is reached once patient is without menses for one year.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	28 Sep 2020 13:56:30
User opened query 'Per CDM: In the Medical History form the date for "Post-Menopausal" is given as "UN UNK 1998". Please review the date of surgery field in this form and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Sep 2020 08:50:00
User entered 'un UNK 1997'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:57

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:02:57

US3012131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

US3012131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:03:44
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Folder: Screening

Form: Risk of Exposure

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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) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

US3012131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:03:44
	(b) (4)	

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:03:44
	(b) (4)	

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0' reason for change: Data Entry Error	(b) (4) Pamela Fidler (b) (4)	16 Nov 2020 14:31:48
User entered '1'	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:03:44

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Folder: Screening

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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) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	12 Feb 2021 20:26:51
User entered '1' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4) (b) (4)	16 Nov 2020 14:31:48
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:03:44

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '0'	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:03:44

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:41:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered empty.	(b) (4) Katherine Davis (b) (4)	13 Aug 2020 23:03:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 21:02:35

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '13 Aug 2020'	Jennifer Leyva (b) (4)	13 Aug 2020 21:02:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4)	13 Aug 2020 21:02:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

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[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'VISIT1'	(b) (4), (b) (6) System	13 Aug 2020 21:02:35

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '13 AUG 2020'	RWS_ENDPOINT	13 Aug 2020 20:59:23
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:18:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:18:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 20:59:23
User entered '186033' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 20:59:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '>=65 years (3)'	RWS_ENDPOINT	13 Aug 2020 20:59:23
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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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)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:04:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

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)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:04:04

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Folder: Visit 1 Day 1

Form: Randomization

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Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'No (N)'	Katherine Davis (b) (4)	13 Aug 2020 23:04:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'No (N)'	Katherine Davis (b) (4)	13 Aug 2020 23:04:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'No (N)'	Katherine Davis (b) (4)	13 Aug 2020 23:04:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User closed query 'Per CDM: this field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 06:32:39
	(b) (4), (b) (6)	
Query 'Per CDM: this field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	28 Oct 2020 14:43:30
	(b) (4)	
	(b) (4)	
User entered 'No (N)'	Pamela Fidler (b) (4)	28 Oct 2020 14:43:24
	(b) (4)	
	(b) (4)	
User opened query 'Per CDM: this field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:15:04
	(b) (4), (b) (6)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:14
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:07:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Sep 2020 18:32:56
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 15:08:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 15:07:57
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	23 Aug 2020 20:24:27
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:05:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4)	11 Sep 2020 15:07:57
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Sep 2020 18:32:56
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 15:08:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 15:07:57
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	23 Aug 2020 20:24:27
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:05:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4)	11 Sep 2020 15:07:57
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '13 Aug 2020'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:05:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '14:36'	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '13 Aug 2020 14:36'	(b) (4), (b) (6) System	13 Aug 2020 23:05:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '98.7' F	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Oral (Oral)'	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

US3012131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '71'	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'bpm'	(b) (4), (b) (6) System	13 Aug 2020 23:05:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '14'	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'breaths/min'	(b) (4), (b) (6) System	13 Aug 2020 23:05:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '126'	(b) (4)	
	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

US3012131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'mmHg'	(b) (4), (b) (6) System	13 Aug 2020 23:05:10

US3012131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '82'	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

US3012131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'mmHg'	(b) (4), (b) (6) System	13 Aug 2020 23:05:10

US3012131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Sep 2020 18:32:56
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 15:08:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 15:07:57
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	23 Aug 2020 20:24:27
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:05:10

US3012131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4)	11 Sep 2020 15:07:57
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 23:05:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:05:59

US3012131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Aug 2020 23:05:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '13 Aug 2020'	(b) (4) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:05:59

US3012131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	17 Aug 2020 06:54:04
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post vitals collected 30 min post not 60 min ' (Site from System).	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:06:24
User opened 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).		13 Aug 2020 23:05:59
User entered '17:21'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:05:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '13 Aug 2020 17:21'	(b) (4), (b) (6) System	13 Aug 2020 23:05:59

US3012131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '97.7' F	Katherine Davis (b) (4)	13 Aug 2020 23:05:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Oral (Oral)'	Katherine Davis (b) (4)	13 Aug 2020 23:05:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 23:05:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '68'	Katherine Davis (b) (4)	13 Aug 2020 23:05:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'bpm'	(b) (4), (b) (6) System	13 Aug 2020 23:05:59

US3012131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '14'	(b) (4)	
	Katherine Davis (b) (4)	13 Aug 2020 23:05:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'breaths/min'	(b) (4), (b) (6) System	13 Aug 2020 23:05:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '132'	Katherine Davis (b) (4)	13 Aug 2020 23:05:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'mmHg'	(b) (4), (b) (6) System	13 Aug 2020 23:05:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '76'	Katherine Davis (b) (4)	13 Aug 2020 23:05:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'mmHg'	(b) (4), (b) (6) System	13 Aug 2020 23:05:59

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'No (N)'	Katherine Davis (b) (4)	13 Aug 2020 23:06:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 23:06:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	13 Aug 2020 22:16:58

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	13 Aug 2020 22:16:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

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)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	13 Aug 2020 22:16:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '13 Aug 2020'	Jennifer Leyva (b) (4)	13 Aug 2020 22:16:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '16:27'	Jennifer Leyva (b) (4)	13 Aug 2020 22:16:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '13 Aug 2020 16:27'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Jennifer Leyva (b) (4)	13 Aug 2020 22:16:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'ONCE'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Aug 2020 23:07:16
	(b) (4)	

US3012131

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '13 Aug 2020'	Katherine Davis (b) (4)	13 Aug 2020 23:07:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '15:53'	Katherine Davis (b) (4)	13 Aug 2020 23:07:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '13 Aug 2020 15:53'	(b) (4), (b) (6) System	13 Aug 2020 23:07:16

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '13 Aug 2020'	Katherine Davis (b) (4)	13 Aug 2020 23:07:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:07:38

US3012131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Aug 2020 23:07:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '15:06'	Katherine Davis (b) (4)	13 Aug 2020 23:07:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '13 Aug 2020 15:06'	(b) (4), (b) (6) System	13 Aug 2020 23:07:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Katherine Davis (b) (4) (b) (4)	13 Aug 2020 23:07:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'No (N)'	Katherine Davis (b) (4)	13 Aug 2020 23:07:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 23:07:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered empty.	(b) (4), (b) (6) System	13 Aug 2020 23:07:38

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	13 Aug 2020 23:07:43
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'I'	(b) (4), (b) (6) System	13 Aug 2020 23:07:43

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:24:05', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '415492c9-c568-42e4-a5c6-a14963df3ef1' User entered 'Yes (Y)'	System	13 Aug 2020 22:27:26
	System	13 Aug 2020 22:27:26

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:25:05', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '415492c9-c568-42e4-a5c6-a14963df3ef1' User entered '97.7'	System	13 Aug 2020 22:27:26
	System	13 Aug 2020 22:27:26

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:27:07', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '415492c9-c568-42e4-a5c6-a14963df3ef1' User entered 'No (N)'	System	13 Aug 2020 22:27:26
	System	13 Aug 2020 22:27:26

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:27:21', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '415492c9-c568-42e4-a5c6-a14963df3ef1' User entered '13 Aug 2020 17:27'	System	13 Aug 2020 22:27:26
	System	13 Aug 2020 22:27:26

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Aug 2020 16:47'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Aug 2020 19:17'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:08:55', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0ffcdddec-142c-4e92-ad01-5279027d69aa' User entered 'Yes (Y)'	System	14 Aug 2020 06:09:24
	System	14 Aug 2020 06:09:24

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:08', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0ffcddec-142c-4e92-ad01-5279027d69aa' User entered '97.7'	System	14 Aug 2020 06:09:24
	System	14 Aug 2020 06:09:24

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:12', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0ffcddec-142c-4e92-ad01-5279027d69aa'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Aug 2020 06:09:24

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:23', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0ffcddec-142c-4e92-ad01-5279027d69aa' User entered '14 Aug 2020 01:09'	System	14 Aug 2020 06:09:24
	System	14 Aug 2020 06:09:24

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Aug 2020 20:12'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 2'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:05:59', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'e58facb8-6912-4d89-b553-c19a4d3577d9' User entered 'Yes (Y)'	System	15 Aug 2020 01:06:37
	System	15 Aug 2020 01:06:37

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:06:12', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'e58facb8-6912-4d89-b553-c19a4d3577d9' User entered '97.7'	System	15 Aug 2020 01:06:37
	System	15 Aug 2020 01:06:37

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:06:19', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'e58facb8-6912-4d89-b553-c19a4d3577d9' User entered 'No (N)'	System	15 Aug 2020 01:06:37
	System	15 Aug 2020 01:06:37

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:06:35', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'e58facb8-6912-4d89-b553-c19a4d3577d9' User entered '14 Aug 2020 20:06'	System	15 Aug 2020 01:06:37
	System	15 Aug 2020 01:06:37

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 3'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:06:20', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a3075a6d-d73b-4dc8-a1af-c0884551eb68' User entered 'Yes (Y)'	System	16 Aug 2020 00:06:59
	System	16 Aug 2020 00:06:59

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:06:41', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a3075a6d-d73b-4dc8-a1af-c0884551eb68' User entered '98.1'	System	16 Aug 2020 00:06:59
	System	16 Aug 2020 00:06:59

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:06:47', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a3075a6d-d73b-4dc8-a1af-c0884551eb68' User entered 'No (N)'	System	16 Aug 2020 00:06:59
	System	16 Aug 2020 00:06:59

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:06:57', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a3075a6d-d73b-4dc8-a1af-c0884551eb68' User entered '15 Aug 2020 19:06'	System	16 Aug 2020 00:06:59
	System	16 Aug 2020 00:06:59

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 4'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:39:21', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0a413a8a-2626-4bf8-9131-c212aa942171' User entered 'Yes (Y)'	System	16 Aug 2020 23:40:21
	System	16 Aug 2020 23:40:21

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:39:31', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0a413a8a-2626-4bf8-9131-c212aa942171' User entered '97.8'	System	16 Aug 2020 23:40:21
	System	16 Aug 2020 23:40:21

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:40:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0a413a8a-2626-4bf8-9131-c212aa942171' User entered 'No (N)'	System	16 Aug 2020 23:40:21
	System	16 Aug 2020 23:40:21

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:40:16', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0a413a8a-2626-4bf8-9131-c212aa942171' User entered '16 Aug 2020 18:40'	System	16 Aug 2020 23:40:21
	System	16 Aug 2020 23:40:21

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 5'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:43:10', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0c86e728-fe5c-4409-a807-91ec280ed7e1' User entered 'Yes (Y)'	System	17 Aug 2020 23:43:41
	System	17 Aug 2020 23:43:41

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:43:22', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0c86e728-fe5c-4409-a807-91ec280ed7e1' User entered '97.8'	System	17 Aug 2020 23:43:41
	System	17 Aug 2020 23:43:41

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:43:26', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0c86e728-fe5c-4409-a807-91ec280ed7e1' User entered 'No (N)'	System	17 Aug 2020 23:43:41
	System	17 Aug 2020 23:43:41

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:43:38', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0c86e728-fe5c-4409-a807-91ec280ed7e1' User entered '17 Aug 2020 18:43'	System	17 Aug 2020 23:43:41
	System	17 Aug 2020 23:43:41

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 6'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:24:18', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '19da97f1-856e-44b6-8f08-3f74c3f8da5d' User entered 'Yes (Y)'	System	18 Aug 2020 23:24:38
	System	18 Aug 2020 23:24:38

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:24:24', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '19da97f1-856e-44b6-8f08-3f74c3f8da5d' User entered '97.7'	System	18 Aug 2020 23:24:38
	System	18 Aug 2020 23:24:38

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:24:29', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '19da97f1-856e-44b6-8f08-3f74c3f8da5d' User entered 'No (N)'	System	18 Aug 2020 23:24:38
	System	18 Aug 2020 23:24:38

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:24:36', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '19da97f1-856e-44b6-8f08-3f74c3f8da5d' User entered '18 Aug 2020 18:24'	System	18 Aug 2020 23:24:38
	System	18 Aug 2020 23:24:38

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 7'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:00:15', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '12a04662-0a70-4ffb-bc9e-dc4d9af1e5f6' User entered 'Yes (Y)'	System	20 Aug 2020 00:00:43
	System	20 Aug 2020 00:00:43

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:00:23', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '12a04662-0a70-4ffb-bc9e-dc4d9af1e5f6' User entered '97.8'	System	20 Aug 2020 00:00:43
	System	20 Aug 2020 00:00:43

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:00:30', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '12a04662-0a70-4ffb-bc9e-dc4d9af1e5f6'	System	20 Aug 2020 00:00:43
User entered 'No (N)'	System	20 Aug 2020 00:00:43

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:00:38', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '12a04662-0a70-4ffb-bc9e-dc4d9af1e5f6' User entered '19 Aug 2020 19:00'	System	20 Aug 2020 00:00:43
	System	20 Aug 2020 00:00:43

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:28:03', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2fba4805-bb11-4d57-b380-6f1ea56544e3' User entered 'None (1)'	System	13 Aug 2020 22:32:46
	System	13 Aug 2020 22:32:46

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:31:57', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2fba4805-bb11-4d57-b380-6f1ea56544e3' User entered 'No (N)'	System	13 Aug 2020 22:32:46
	System	13 Aug 2020 22:32:46

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:32:14', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2fba4805-bb11-4d57-b380-6f1ea56544e3' User entered 'No (N)'	System	13 Aug 2020 22:32:46
	System	13 Aug 2020 22:32:46

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:32:26', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2fba4805-bb11-4d57-b380-6f1ea56544e3' User entered 'None (1)'	System	13 Aug 2020 22:32:46
	System	13 Aug 2020 22:32:46

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:32:44', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2fba4805-bb11-4d57-b380-6f1ea56544e3' User entered '13 Aug 2020 17:32'	System	13 Aug 2020 22:32:46
	System	13 Aug 2020 22:32:46

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Aug 2020 16:47'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Aug 2020 19:17'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:28', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '9201f7e2-34f3-4a8a-9ff7-eee669504bb7' User entered 'None (1)'	System	14 Aug 2020 06:09:45
	System	14 Aug 2020 06:09:45

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:31', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '9201f7e2-34f3-4a8a-9ff7-eee669504bb7' User entered 'No (N)'	System	14 Aug 2020 06:09:45
	System	14 Aug 2020 06:09:45

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:33', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '9201f7e2-34f3-4a8a-9ff7-eee669504bb7' User entered 'No (N)'	System	14 Aug 2020 06:09:45
	System	14 Aug 2020 06:09:45

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:37', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '9201f7e2-34f3-4a8a-9ff7-eee669504bb7' User entered 'None (1)'	System	14 Aug 2020 06:09:45
	System	14 Aug 2020 06:09:45

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:43', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '9201f7e2-34f3-4a8a-9ff7-eee669504bb7' User entered '14 Aug 2020 01:09'	System	14 Aug 2020 06:09:45
	System	14 Aug 2020 06:09:45

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Aug 2020 20:12'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 2'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:06:59', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a99cc865-f7e7-4060-a35d-c31c62dde60b' User entered 'None (1)'	System	15 Aug 2020 01:07:30
	System	15 Aug 2020 01:07:30

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:07:03', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a99cc865-f7e7-4060-a35d-c31c62dde60b' User entered 'No (N)'	System	15 Aug 2020 01:07:30
	System	15 Aug 2020 01:07:30

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:07:07', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a99cc865-f7e7-4060-a35d-c31c62dde60b' User entered 'No (N)'	System	15 Aug 2020 01:07:30
	System	15 Aug 2020 01:07:30

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:07:15', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a99cc865-f7e7-4060-a35d-c31c62dde60b' User entered 'None (1)'	System	15 Aug 2020 01:07:30
	System	15 Aug 2020 01:07:30

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:07:24', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a99cc865-f7e7-4060-a35d-c31c62dde60b' User entered '14 Aug 2020 20:07'	System	15 Aug 2020 01:07:30
	System	15 Aug 2020 01:07:30

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 3'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:07:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '8360727f-ae3b-49cf-a5aa-94040022bd7b' User entered 'None (1)'	System	16 Aug 2020 00:07:33
	System	16 Aug 2020 00:07:33

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:07:09', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '8360727f-ae3b-49cf-a5aa-94040022bd7b' User entered 'No (N)'	System	16 Aug 2020 00:07:33
	System	16 Aug 2020 00:07:33

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:07:14', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '8360727f-ae3b-49cf-a5aa-94040022bd7b' User entered 'No (N)'	System	16 Aug 2020 00:07:33
	System	16 Aug 2020 00:07:33

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:07:20', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '8360727f-ae3b-49cf-a5aa-94040022bd7b' User entered 'None (1)'	System	16 Aug 2020 00:07:33
	System	16 Aug 2020 00:07:33

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:07:30', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '8360727f-ae3b-49cf-a5aa-94040022bd7b' User entered '15 Aug 2020 19:07'	System	16 Aug 2020 00:07:33
	System	16 Aug 2020 00:07:33

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 4'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:40:25', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ae9b67d6-a7a5-4aa7-a6cb-cb573e58a288' User entered 'None (1)'	System	16 Aug 2020 23:40:53
	System	16 Aug 2020 23:40:53

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:40:29', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ae9b67d6-a7a5-4aa7-a6cb-cb573e58a288' User entered 'No (N)'	System	16 Aug 2020 23:40:53
	System	16 Aug 2020 23:40:53

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:40:32', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ae9b67d6-a7a5-4aa7-a6cb-cb573e58a288' User entered 'No (N)'	System	16 Aug 2020 23:40:53
	System	16 Aug 2020 23:40:53

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:40:39', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ae9b67d6-a7a5-4aa7-a6cb-cb573e58a288' User entered 'None (1)'	System	16 Aug 2020 23:40:53
	System	16 Aug 2020 23:40:53

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:40:49', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ae9b67d6-a7a5-4aa7-a6cb-cb573e58a288' User entered '16 Aug 2020 18:40'	System	16 Aug 2020 23:40:53
	System	16 Aug 2020 23:40:53

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 5'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:43:45', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b6b115f6-1f74-43da-b88d-b18b01741e22'	System	17 Aug 2020 23:44:44
User entered 'None (1)'	System	17 Aug 2020 23:44:44

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:43:50', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b6b115f6-1f74-43da-b88d-b18b01741e22' User entered 'No (N)'	System	17 Aug 2020 23:44:44
	System	17 Aug 2020 23:44:44

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:43:56', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b6b115f6-1f74-43da-b88d-b18b01741e22' User entered 'No (N)'	System	17 Aug 2020 23:44:44
	System	17 Aug 2020 23:44:44

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:44:21', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b6b115f6-1f74-43da-b88d-b18b01741e22'	System	17 Aug 2020 23:44:44
User entered 'None (1)'	System	17 Aug 2020 23:44:44

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:44:41', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b6b115f6-1f74-43da-b88d-b18b01741e22' User entered '17 Aug 2020 18:44'	System	17 Aug 2020 23:44:44
	System	17 Aug 2020 23:44:44

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 6'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:24:44', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a650fc3e-e725-4879-85bd-1a7765976701' User entered 'None (1)'	System	18 Aug 2020 23:25:14
	System	18 Aug 2020 23:25:14

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:24:47', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a650fc3e-e725-4879-85bd-1a7765976701' User entered 'No (N)'	System	18 Aug 2020 23:25:14
	System	18 Aug 2020 23:25:14

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:24:56', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a650fc3e-e725-4879-85bd-1a7765976701' User entered 'No (N)'	System	18 Aug 2020 23:25:14
	System	18 Aug 2020 23:25:14

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:25:02', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a650fc3e-e725-4879-85bd-1a7765976701' User entered 'None (1)'	System	18 Aug 2020 23:25:14
	System	18 Aug 2020 23:25:14

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:25:11', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a650fc3e-e725-4879-85bd-1a7765976701' User entered '18 Aug 2020 18:25'	System	18 Aug 2020 23:25:14
	System	18 Aug 2020 23:25:14

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 7'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:01:10', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '85eb098e-5654-4303-8f34-8cb39514be79' User entered 'None (1)'	System	20 Aug 2020 00:01:39
	System	20 Aug 2020 00:01:39

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:01:15', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '85eb098e-5654-4303-8f34-8cb39514be79' User entered 'No (N)'	System	20 Aug 2020 00:01:39
	System	20 Aug 2020 00:01:39

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:01:19', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '85eb098e-5654-4303-8f34-8cb39514be79' User entered 'No (N)'	System	20 Aug 2020 00:01:39
	System	20 Aug 2020 00:01:39

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:01:24', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '85eb098e-5654-4303-8f34-8cb39514be79' User entered 'None (1)'	System	20 Aug 2020 00:01:39
	System	20 Aug 2020 00:01:39

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:01:34', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '85eb098e-5654-4303-8f34-8cb39514be79' User entered '19 Aug 2020 19:01'	System	20 Aug 2020 00:01:39
	System	20 Aug 2020 00:01:39

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:33:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a0614833-8421-4893-b8ee-0b80331d1b79' User entered 'None (0)'	System	13 Aug 2020 22:34:44
	System	13 Aug 2020 22:34:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:33:12', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a0614833-8421-4893-b8ee-0b80331d1b79' User entered 'None (0)'	System	13 Aug 2020 22:34:44
	System	13 Aug 2020 22:34:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:33:16', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a0614833-8421-4893-b8ee-0b80331d1b79' User entered 'None (0)'	System	13 Aug 2020 22:34:44
	System	13 Aug 2020 22:34:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:33:20', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a0614833-8421-4893-b8ee-0b80331d1b79' User entered 'None (0)'	System	13 Aug 2020 22:34:44
	System	13 Aug 2020 22:34:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:33:27', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a0614833-8421-4893-b8ee-0b80331d1b79' User entered 'None (0)'	System	13 Aug 2020 22:34:44
	System	13 Aug 2020 22:34:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:33:33', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a0614833-8421-4893-b8ee-0b80331d1b79' User entered 'None (0)'	System	13 Aug 2020 22:34:44
	System	13 Aug 2020 22:34:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:34:18', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a0614833-8421-4893-b8ee-0b80331d1b79' User entered 'No (N)'	System	13 Aug 2020 22:34:44
	System	13 Aug 2020 22:34:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-13T17:34:25', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a0614833-8421-4893-b8ee-0b80331d1b79' User entered '13 Aug 2020 17:34'	System	13 Aug 2020 22:34:44
	System	13 Aug 2020 22:34:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Aug 2020 16:47'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Aug 2020 19:17'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:48', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7b4a5dcc-0020-46f7-98cf-3218714b1c9b' User entered 'None (0)'	System	14 Aug 2020 06:10:08
	System	14 Aug 2020 06:10:08

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:50', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7b4a5dcc-0020-46f7-98cf-3218714b1c9b' User entered 'None (0)'	System	14 Aug 2020 06:10:08
	System	14 Aug 2020 06:10:08

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:52', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7b4a5dcc-0020-46f7-98cf-3218714b1c9b' User entered 'None (0)'	System	14 Aug 2020 06:10:08
	System	14 Aug 2020 06:10:08

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:54', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7b4a5dcc-0020-46f7-98cf-3218714b1c9b' User entered 'None (0)'	System	14 Aug 2020 06:10:08
	System	14 Aug 2020 06:10:08

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:56', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7b4a5dcc-0020-46f7-98cf-3218714b1c9b' User entered 'None (0)'	System	14 Aug 2020 06:10:08
	System	14 Aug 2020 06:10:08

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:09:59', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7b4a5dcc-0020-46f7-98cf-3218714b1c9b' User entered 'None (0)'	System	14 Aug 2020 06:10:08
	System	14 Aug 2020 06:10:08

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:10:02', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7b4a5dcc-0020-46f7-98cf-3218714b1c9b' User entered 'No (N)'	System	14 Aug 2020 06:10:08
	System	14 Aug 2020 06:10:08

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T01:10:05', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7b4a5dcc-0020-46f7-98cf-3218714b1c9b' User entered '14 Aug 2020 01:10'	System	14 Aug 2020 06:10:08
	System	14 Aug 2020 06:10:08

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Aug 2020 20:12'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 2'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:07:36', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '3cb11acb-c6f9-4a70-82d8-d481b42cd917' User entered 'None (0)'	System	15 Aug 2020 01:08:44
	System	15 Aug 2020 01:08:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:07:48', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '3cb11acb-c6f9-4a70-82d8-d481b42cd917' User entered 'None (0)'	System	15 Aug 2020 01:08:44
	System	15 Aug 2020 01:08:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:07:51', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '3cb11acb-c6f9-4a70-82d8-d481b42cd917' User entered 'None (0)'	System	15 Aug 2020 01:08:44
	System	15 Aug 2020 01:08:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:08:01', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '3cb11acb-c6f9-4a70-82d8-d481b42cd917' User entered 'None (0)'	System	15 Aug 2020 01:08:44
	System	15 Aug 2020 01:08:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:08:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '3cb11acb-c6f9-4a70-82d8-d481b42cd917' User entered 'None (0)'	System	15 Aug 2020 01:08:44
	System	15 Aug 2020 01:08:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:08:07', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '3cb11acb-c6f9-4a70-82d8-d481b42cd917' User entered 'None (0)'	System	15 Aug 2020 01:08:44
	System	15 Aug 2020 01:08:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:08:12', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '3cb11acb-c6f9-4a70-82d8-d481b42cd917' User entered 'No (N)'	System	15 Aug 2020 01:08:44
	System	15 Aug 2020 01:08:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-14T20:08:24', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '3cb11acb-c6f9-4a70-82d8-d481b42cd917' User entered '14 Aug 2020 20:08'	System	15 Aug 2020 01:08:44
	System	15 Aug 2020 01:08:44

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 3'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:07:40', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f1272119-d2d7-48da-bac8-34d5ca22255d' User entered 'None (0)'	System	16 Aug 2020 00:08:28
	System	16 Aug 2020 00:08:28

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:07:44', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f1272119-d2d7-48da-bac8-34d5ca22255d' User entered 'None (0)'	System	16 Aug 2020 00:08:28
	System	16 Aug 2020 00:08:28

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:07:49', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f1272119-d2d7-48da-bac8-34d5ca22255d' User entered 'None (0)'	System	16 Aug 2020 00:08:28
	System	16 Aug 2020 00:08:28

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:07:57', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f1272119-d2d7-48da-bac8-34d5ca22255d' User entered 'None (0)'	System	16 Aug 2020 00:08:28
	System	16 Aug 2020 00:08:28

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:08:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f1272119-d2d7-48da-bac8-34d5ca22255d' User entered 'None (0)'	System	16 Aug 2020 00:08:28
	System	16 Aug 2020 00:08:28

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:08:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f1272119-d2d7-48da-bac8-34d5ca22255d' User entered 'None (0)'	System	16 Aug 2020 00:08:28
	System	16 Aug 2020 00:08:28

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:08:11', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f1272119-d2d7-48da-bac8-34d5ca22255d' User entered 'No (N)'	System	16 Aug 2020 00:08:28
	System	16 Aug 2020 00:08:28

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-15T19:08:25', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f1272119-d2d7-48da-bac8-34d5ca22255d' User entered '15 Aug 2020 19:08'	System	16 Aug 2020 00:08:28
	System	16 Aug 2020 00:08:28

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 4'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:40:59', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'afe2484a-e4cf-4e54-8078-9d51de6bd13a' User entered 'None (0)'	System	16 Aug 2020 23:42:16
	System	16 Aug 2020 23:42:16

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:41:02', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'afe2484a-e4cf-4e54-8078-9d51de6bd13a' User entered 'None (0)'	System	16 Aug 2020 23:42:16
	System	16 Aug 2020 23:42:16

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:41:06', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'afe2484a-e4cf-4e54-8078-9d51de6bd13a' User entered 'None (0)'	System	16 Aug 2020 23:42:16
	System	16 Aug 2020 23:42:16

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:41:10', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'afe2484a-e4cf-4e54-8078-9d51de6bd13a' User entered 'None (0)'	System	16 Aug 2020 23:42:16
	System	16 Aug 2020 23:42:16

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:41:13', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'afe2484a-e4cf-4e54-8078-9d51de6bd13a' User entered 'None (0)'	System	16 Aug 2020 23:42:16
	System	16 Aug 2020 23:42:16

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:41:16', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'afe2484a-e4cf-4e54-8078-9d51de6bd13a' User entered 'None (0)'	System	16 Aug 2020 23:42:16
	System	16 Aug 2020 23:42:16

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:41:38', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'afe2484a-e4cf-4e54-8078-9d51de6bd13a' User entered 'No (N)'	System	16 Aug 2020 23:42:16
	System	16 Aug 2020 23:42:16

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-16T18:42:12', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'afe2484a-e4cf-4e54-8078-9d51de6bd13a' User entered '16 Aug 2020 18:42'	System	16 Aug 2020 23:42:16
	System	16 Aug 2020 23:42:16

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 5'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:44:49', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd26a6aa5-80d3-486c-bce7-092fd88dd793' User entered 'None (0)'	System	17 Aug 2020 23:45:37
	System	17 Aug 2020 23:45:37

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:44:54', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd26a6aa5-80d3-486c-bce7-092fd88dd793' User entered 'None (0)'	System	17 Aug 2020 23:45:37
	System	17 Aug 2020 23:45:37

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:44:59', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd26a6aa5-80d3-486c-bce7-092fd88dd793' User entered 'None (0)'	System	17 Aug 2020 23:45:37
	System	17 Aug 2020 23:45:37

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:45:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd26a6aa5-80d3-486c-bce7-092fd88dd793' User entered 'None (0)'	System	17 Aug 2020 23:45:37
	System	17 Aug 2020 23:45:37

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:45:07', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd26a6aa5-80d3-486c-bce7-092fd88dd793' User entered 'None (0)'	System	17 Aug 2020 23:45:37
	System	17 Aug 2020 23:45:37

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:45:10', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd26a6aa5-80d3-486c-bce7-092fd88dd793' User entered 'None (0)'	System	17 Aug 2020 23:45:37
	System	17 Aug 2020 23:45:37

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:45:24', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd26a6aa5-80d3-486c-bce7-092fd88dd793' User entered 'No (N)'	System	17 Aug 2020 23:45:37
	System	17 Aug 2020 23:45:37

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-17T18:45:35', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd26a6aa5-80d3-486c-bce7-092fd88dd793' User entered '17 Aug 2020 18:45'	System	17 Aug 2020 23:45:37
	System	17 Aug 2020 23:45:37

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 6'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:25:19', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0bee097c-cc36-42bb-bfb1-466fad776f07' User entered 'None (0)'	System	18 Aug 2020 23:26:10
	System	18 Aug 2020 23:26:10

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:25:22', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0bee097c-cc36-42bb-bfb1-466fad776f07' User entered 'None (0)'	System	18 Aug 2020 23:26:10
	System	18 Aug 2020 23:26:10

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:25:27', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0bee097c-cc36-42bb-bfb1-466fad776f07' User entered 'None (0)'	System	18 Aug 2020 23:26:10
	System	18 Aug 2020 23:26:10

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:25:33', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0bee097c-cc36-42bb-bfb1-466fad776f07' User entered 'None (0)'	System	18 Aug 2020 23:26:10
	System	18 Aug 2020 23:26:10

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:25:38', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0bee097c-cc36-42bb-bfb1-466fad776f07' User entered 'None (0)'	System	18 Aug 2020 23:26:10
	System	18 Aug 2020 23:26:10

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:25:41', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0bee097c-cc36-42bb-bfb1-466fad776f07' User entered 'None (0)'	System	18 Aug 2020 23:26:10
	System	18 Aug 2020 23:26:10

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:25:59', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0bee097c-cc36-42bb-bfb1-466fad776f07' User entered 'No (N)'	System	18 Aug 2020 23:26:10
	System	18 Aug 2020 23:26:10

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-18T18:26:08', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '0bee097c-cc36-42bb-bfb1-466fad776f07' User entered '18 Aug 2020 18:26'	System	18 Aug 2020 23:26:10
	System	18 Aug 2020 23:26:10

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 7'	System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:01:43', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7cd0f8a9-c732-479d-bec2-2d425818ce15' User entered 'None (0)'	System	20 Aug 2020 00:02:48
	System	20 Aug 2020 00:02:48

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:01:49', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7cd0f8a9-c732-479d-bec2-2d425818ce15' User entered 'None (0)'	System	20 Aug 2020 00:02:48
	System	20 Aug 2020 00:02:48

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:02:02', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7cd0f8a9-c732-479d-bec2-2d425818ce15' User entered 'None (0)'	System	20 Aug 2020 00:02:48
	System	20 Aug 2020 00:02:48

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:02:09', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7cd0f8a9-c732-479d-bec2-2d425818ce15' User entered 'None (0)'	System	20 Aug 2020 00:02:48
	System	20 Aug 2020 00:02:48

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:02:15', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7cd0f8a9-c732-479d-bec2-2d425818ce15' User entered 'None (0)'	System	20 Aug 2020 00:02:48
	System	20 Aug 2020 00:02:48

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:02:23', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7cd0f8a9-c732-479d-bec2-2d425818ce15' User entered 'None (0)'	System	20 Aug 2020 00:02:48
	System	20 Aug 2020 00:02:48

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:02:31', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7cd0f8a9-c732-479d-bec2-2d425818ce15' User entered 'No (N)'	System	20 Aug 2020 00:02:48
	System	20 Aug 2020 00:02:48

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-08-19T19:02:44', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7cd0f8a9-c732-479d-bec2-2d425818ce15' User entered '19 Aug 2020 19:02'	System	20 Aug 2020 00:02:48
	System	20 Aug 2020 00:02:48

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Michelle Listz (b) (4)	25 Aug 2020 20:38:35
	(b) (4)	

US3012131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Aug 2020 07:23:05
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date of contact is correct' (Site from System).	Michelle Listz (b) (4) (b) (4)	25 Aug 2020 20:39:02
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Aug 2020 20:38:35
User entered '25 Aug 2020'	Michelle Listz (b) (4) (b) (4)	25 Aug 2020 20:38:35

US3012131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Michelle Listz (b) (4)	25 Aug 2020 20:38:35
	(b) (4)	

US3012131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Michelle Listz (b) (4)	25 Aug 2020 20:38:35
	(b) (4)	

US3012131

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Michelle Listz (b) (4)	25 Aug 2020 20:39:13
	(b) (4)	

US3012131

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'I'	(b) (4), (b) (6) System	25 Aug 2020 20:39:13

US3012131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Yes (Y)'	Michelle Listz (b) (4)	03 Sep 2020 00:25:49
	(b) (4)	

US3012131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:30
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	03 Sep 2020 07:29:24
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date of Contact is correct.' (Site from System).	Michelle Listz (b) (4) (b) (4)	03 Sep 2020 00:25:59
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Sep 2020 00:25:49
User entered '1 Sep 2020'	Michelle Listz (b) (4) (b) (4)	03 Sep 2020 00:25:49

US3012131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Michelle Listz (b) (4)	03 Sep 2020 00:25:49
	(b) (4)	

US3012131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered empty.	Michelle Listz (b) (4)	03 Sep 2020 00:25:49
	(b) (4)	

US3012131

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Yes (Y)'	Michelle Listz (b) (4)	03 Sep 2020 00:26:05
	(b) (4)	

US3012131

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'I'	(b) (4), (b) (6) System	03 Sep 2020 00:26:05

US3012131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Yes (Y)'	Tambra Dora (b) (4)	08 Sep 2020 14:03:52
	(b) (4)	

US3012131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered '4 Sep 2020'	Tambra Dora (b) (4)	08 Sep 2020 14:03:52
	(b) (4)	

US3012131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	08 Sep 2020 14:03:52
	(b) (4)	

US3012131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered empty.	Tambra Dora (b) (4)	08 Sep 2020 14:03:52
	(b) (4)	

US3012131

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Yes (Y)'	Tambra Dora (b) (4)	08 Sep 2020 14:03:56
	(b) (4)	

US3012131

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'I'	(b) (4), (b) (6) System	08 Sep 2020 14:03:56

US3012131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Sep 2020 16:07:28
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '10 Sep 2020'	Jennifer Leyva (b) (4)	10 Sep 2020 16:07:28
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4)	10 Sep 2020 16:07:28
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'VISIT2'	(b) (4), (b) (6) System	10 Sep 2020 16:07:28

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Jennifer Leyva (b) (4) (b) (4)	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '10 Sep 2020'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '09:51'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '10 Sep 2020 09:51'	(b) (4), (b) (6) System	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '98.4' F	Jennifer Leyva (b) (4)	10 Sep 2020 16:07:52
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Oral (Oral)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	10 Sep 2020 16:07:52
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '72'	Jennifer Leyva (b) (4)	10 Sep 2020 16:07:52
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'bpm'	(b) (4), (b) (6) System	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '14'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'breaths/min'	(b) (4), (b) (6) System	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '120'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'mmHg'	(b) (4), (b) (6) System	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '78'	Jennifer Leyva (b) (4)	10 Sep 2020 16:07:52
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'mmHg'	(b) (4), (b) (6) System	10 Sep 2020 16:07:52

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '10 Sep 2020'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '12:21'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '10 Sep 2020 12:21'	(b) (4), (b) (6) System	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '97.9' F	Jennifer Leyva (b) (4)	11 Sep 2020 14:53:53
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4)	11 Sep 2020 14:53:53
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	11 Sep 2020 14:53:53
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '56'	(b) (4)	
	Jennifer Leyva (b) (4)	11 Sep 2020 14:53:53
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'bpm'	(b) (4), (b) (6) System	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '14'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '118'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '74'	Jennifer Leyva (b) (4)	11 Sep 2020 14:53:53
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 14:53:53

US3012131

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Sep 2020 16:07:59
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '10 Sep 2020'	Jennifer Leyva (b) (4)	10 Sep 2020 16:07:59
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Sep 2020 16:52:32
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	10 Sep 2020 16:52:32
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

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)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	10 Sep 2020 16:52:32
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '10 Sep 2020'	Jennifer Leyva (b) (4)	10 Sep 2020 16:52:32
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '11:11'	Jennifer Leyva (b) (4)	10 Sep 2020 16:52:32
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '10 Sep 2020 11:11'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	10 Sep 2020 16:52:32

US3012131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'ONCE'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Sep 2020 16:08:18
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '10 Sep 2020'	Jennifer Leyva (b) (4)	10 Sep 2020 16:08:18
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '10:34'	Jennifer Leyva (b) (4)	10 Sep 2020 16:08:18
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '10 Sep 2020 10:34'	(b) (4), (b) (6) System	10 Sep 2020 16:08:18

US3012131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '10 Sep 2020'	Jennifer Leyva (b) (4)	10 Sep 2020 16:08:30
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Jennifer Leyva (b) (4) (b) (4)	10 Sep 2020 16:08:30

US3012131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Sep 2020 16:08:30
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '10:17'	Jennifer Leyva (b) (4)	10 Sep 2020 16:08:30
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '10 Sep 2020 10:17'	(b) (4), (b) (6) System	10 Sep 2020 16:08:30

US3012131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Jennifer Leyva (b) (4) (b) (4)	10 Sep 2020 16:08:30

US3012131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'No (N)'	Jennifer Leyva (b) (4)	10 Sep 2020 16:08:30
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	10 Sep 2020 16:08:30
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 16:08:30

US3012131

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	10 Sep 2020 16:08:37
	(b) (4)	

US3012131

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'I'	(b) (4), (b) (6) System	10 Sep 2020 16:08:37

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:13:33', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7ca1e875-468d-498a-92a1-f876ea35a702' User entered 'Yes (Y)'	System	10 Sep 2020 17:14:41
	System	10 Sep 2020 17:14:41

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:14:03', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7ca1e875-468d-498a-92a1-f876ea35a702' User entered '97.9'	System	10 Sep 2020 17:14:41
	System	10 Sep 2020 17:14:41

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:14:29', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7ca1e875-468d-498a-92a1-f876ea35a702' User entered 'No (N)'	System	10 Sep 2020 17:14:41
	System	10 Sep 2020 17:14:41

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:14:40', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7ca1e875-468d-498a-92a1-f876ea35a702' User entered '10 Sep 2020 12:14'	System	10 Sep 2020 17:14:41
	System	10 Sep 2020 17:14:41

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '10 Sep 2020 11:31'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '10 Sep 2020 14:01'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:26:41', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '4dc4b386-b746-4936-a498-e3acc4ea30c5' User entered 'Yes (Y)'	System	11 Sep 2020 00:27:03
	System	11 Sep 2020 00:27:03

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:26:49', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '4dc4b386-b746-4936-a498-e3acc4ea30c5' User entered '97.8'	System	11 Sep 2020 00:27:03
	System	11 Sep 2020 00:27:03

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:26:53', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '4dc4b386-b746-4936-a498-e3acc4ea30c5' User entered 'No (N)'	System	11 Sep 2020 00:27:03
	System	11 Sep 2020 00:27:03

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:26:59', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '4dc4b386-b746-4936-a498-e3acc4ea30c5' User entered '10 Sep 2020 19:26'	System	11 Sep 2020 00:27:03
	System	11 Sep 2020 00:27:03

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '10 Sep 2020 14:56'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 2'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:03:27', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '58a5050f-ca5b-43a2-bf6f-b0dbdd98213e' User entered 'Yes (Y)'	System	11 Sep 2020 23:03:49
	System	11 Sep 2020 23:03:49

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:03:34', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '58a5050f-ca5b-43a2-bf6f-b0dbdd98213e' User entered '98.6'	System	11 Sep 2020 23:03:49
	System	11 Sep 2020 23:03:49

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:03:38', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '58a5050f-ca5b-43a2-bf6f-b0dbdd98213e' User entered 'No (N)'	System	11 Sep 2020 23:03:49
	System	11 Sep 2020 23:03:49

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:03:47', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '58a5050f-ca5b-43a2-bf6f-b0dbdd98213e' User entered '11 Sep 2020 18:03'	System	11 Sep 2020 23:03:49
	System	11 Sep 2020 23:03:49

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 3'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:17:31', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '6664dfa5-5388-428f-a97b-4a2556220e69' User entered 'Yes (Y)'	System	12 Sep 2020 23:18:11
	System	12 Sep 2020 23:18:11

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:17:53', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '6664dfa5-5388-428f-a97b-4a2556220e69' User entered '97.7'	System	12 Sep 2020 23:18:11
	System	12 Sep 2020 23:18:11

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:18:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '6664dfa5-5388-428f-a97b-4a2556220e69' User entered 'No (N)'	System	12 Sep 2020 23:18:11
	System	12 Sep 2020 23:18:11

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:18:09', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '6664dfa5-5388-428f-a97b-4a2556220e69' User entered '12 Sep 2020 18:18'	System	12 Sep 2020 23:18:11
	System	12 Sep 2020 23:18:11

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 4'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:05:45', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '98e1d388-6780-4ee1-9139-0544c01d68d7' User entered 'Yes (Y)'	System	14 Sep 2020 08:06:32
	System	14 Sep 2020 08:06:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:05:52', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '98e1d388-6780-4ee1-9139-0544c01d68d7' User entered '98.1'	System	14 Sep 2020 08:06:32
	System	14 Sep 2020 08:06:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:21', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '98e1d388-6780-4ee1-9139-0544c01d68d7'	System	14 Sep 2020 08:06:32
User entered 'No (N)'	System	14 Sep 2020 08:06:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:28', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '98e1d388-6780-4ee1-9139-0544c01d68d7' User entered '14 Sep 2020 03:06'	System	14 Sep 2020 08:06:32
	System	14 Sep 2020 08:06:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 5'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:32:34', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'e5ef07ab-e972-40f8-85b2-3a73e2a17ba4' User entered 'Yes (Y)'	System	14 Sep 2020 23:33:22
	System	14 Sep 2020 23:33:22

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:33:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'e5ef07ab-e972-40f8-85b2-3a73e2a17ba4' User entered '97.6'	System	14 Sep 2020 23:33:22
	System	14 Sep 2020 23:33:22

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:33:08', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'e5ef07ab-e972-40f8-85b2-3a73e2a17ba4' User entered 'No (N)'	System	14 Sep 2020 23:33:22
	System	14 Sep 2020 23:33:22

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:33:18', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'e5ef07ab-e972-40f8-85b2-3a73e2a17ba4' User entered '14 Sep 2020 18:33'	System	14 Sep 2020 23:33:22
	System	14 Sep 2020 23:33:22

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 6'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:49:20', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7a63848a-5387-4b88-b79f-876b8813bc17' User entered 'Yes (Y)'	System	15 Sep 2020 23:50:23
	System	15 Sep 2020 23:50:23

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:49:31', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7a63848a-5387-4b88-b79f-876b8813bc17' User entered '97.9'	System	15 Sep 2020 23:50:23
	System	15 Sep 2020 23:50:23

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:49:38', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7a63848a-5387-4b88-b79f-876b8813bc17' User entered 'No (N)'	System	15 Sep 2020 23:50:23
	System	15 Sep 2020 23:50:23

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:49:44', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '7a63848a-5387-4b88-b79f-876b8813bc17' User entered '15 Sep 2020 18:49'	System	15 Sep 2020 23:50:23
	System	15 Sep 2020 23:50:23

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 7'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:33:54', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '68ccc2ef-9b2e-4dbc-98df-edca92452223' User entered 'Yes (Y)'	System	16 Sep 2020 23:34:21
	System	16 Sep 2020 23:34:21

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:33:59', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '68ccc2ef-9b2e-4dbc-98df-edca92452223' User entered '97.1'	System	16 Sep 2020 23:34:21
	System	16 Sep 2020 23:34:21

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:34:03', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '68ccc2ef-9b2e-4dbc-98df-edca92452223' User entered 'No (N)'	System	16 Sep 2020 23:34:21
	System	16 Sep 2020 23:34:21

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:34:16', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '68ccc2ef-9b2e-4dbc-98df-edca92452223' User entered '16 Sep 2020 18:34'	System	16 Sep 2020 23:34:21
	System	16 Sep 2020 23:34:21

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:02', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '09e3cdec-1186-4d74-b87b-09ee96b97e78' User entered 'None (1)'	System	10 Sep 2020 17:15:28
	System	10 Sep 2020 17:15:28

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:07', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '09e3cdec-1186-4d74-b87b-09ee96b97e78' User entered 'No (N)'	System	10 Sep 2020 17:15:28
	System	10 Sep 2020 17:15:28

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:10', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '09e3cdec-1186-4d74-b87b-09ee96b97e78' User entered 'No (N)'	System	10 Sep 2020 17:15:28
	System	10 Sep 2020 17:15:28

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:15', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '09e3cdec-1186-4d74-b87b-09ee96b97e78' User entered 'None (1)'	System	10 Sep 2020 17:15:28
	System	10 Sep 2020 17:15:28

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:25', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '09e3cdec-1186-4d74-b87b-09ee96b97e78' User entered '10 Sep 2020 12:15'	System	10 Sep 2020 17:15:28
	System	10 Sep 2020 17:15:28

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '10 Sep 2020 11:31'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '10 Sep 2020 14:01'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:05', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '18474756-b532-4fde-b6a2-33e46f2b53a7' User entered 'None (1)'	System	11 Sep 2020 00:27:34
	System	11 Sep 2020 00:27:34

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:10', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '18474756-b532-4fde-b6a2-33e46f2b53a7' User entered 'No (N)'	System	11 Sep 2020 00:27:34
	System	11 Sep 2020 00:27:34

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:14', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '18474756-b532-4fde-b6a2-33e46f2b53a7' User entered 'No (N)'	System	11 Sep 2020 00:27:34
	System	11 Sep 2020 00:27:34

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:19', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '18474756-b532-4fde-b6a2-33e46f2b53a7' User entered 'None (1)'	System	11 Sep 2020 00:27:34
	System	11 Sep 2020 00:27:34

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:29', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '18474756-b532-4fde-b6a2-33e46f2b53a7' User entered '10 Sep 2020 19:27'	System	11 Sep 2020 00:27:34
	System	11 Sep 2020 00:27:34

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '10 Sep 2020 14:56'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 2'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:03:53', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '429f263b-3f4e-42f8-8fd1-f98a11361527' User entered 'None (1)'	System	11 Sep 2020 23:04:19
	System	11 Sep 2020 23:04:19

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:03:57', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '429f263b-3f4e-42f8-8fd1-f98a11361527' User entered 'No (N)'	System	11 Sep 2020 23:04:19
	System	11 Sep 2020 23:04:19

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:04:01', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '429f263b-3f4e-42f8-8fd1-f98a11361527' User entered 'No (N)'	System	11 Sep 2020 23:04:19
	System	11 Sep 2020 23:04:19

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:04:05', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '429f263b-3f4e-42f8-8fd1-f98a11361527' User entered 'None (1)'	System	11 Sep 2020 23:04:19
	System	11 Sep 2020 23:04:19

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:04:16', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '429f263b-3f4e-42f8-8fd1-f98a11361527' User entered '11 Sep 2020 18:04'	System	11 Sep 2020 23:04:19
	System	11 Sep 2020 23:04:19

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 3'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:18:16', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'faec70d3-1312-4394-a2fb-40499c2ee5a4'	System	12 Sep 2020 23:18:49
User entered 'None (1)'	System	12 Sep 2020 23:18:49

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:18:21', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'faec70d3-1312-4394-a2fb-40499c2ee5a4' User entered 'No (N)'	System	12 Sep 2020 23:18:49
	System	12 Sep 2020 23:18:49

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:18:25', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'faec70d3-1312-4394-a2fb-40499c2ee5a4' User entered 'No (N)'	System	12 Sep 2020 23:18:49
	System	12 Sep 2020 23:18:49

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:18:30', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'faec70d3-1312-4394-a2fb-40499c2ee5a4'	System	12 Sep 2020 23:18:49
User entered 'None (1)'	System	12 Sep 2020 23:18:49

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:18:47', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'faec70d3-1312-4394-a2fb-40499c2ee5a4' User entered '12 Sep 2020 18:18'	System	12 Sep 2020 23:18:49
	System	12 Sep 2020 23:18:49

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 4'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:39', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f726be85-b074-46af-bf12-afe390123eab' User entered 'None (1)'	System	14 Sep 2020 08:06:52
	System	14 Sep 2020 08:06:52

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:41', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f726be85-b074-46af-bf12-afe390123eab' User entered 'No (N)'	System	14 Sep 2020 08:06:52
	System	14 Sep 2020 08:06:52

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:44', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f726be85-b074-46af-bf12-afe390123eab' User entered 'No (N)'	System	14 Sep 2020 08:06:52
	System	14 Sep 2020 08:06:52

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:46', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f726be85-b074-46af-bf12-afe390123eab' User entered 'None (1)'	System	14 Sep 2020 08:06:52
	System	14 Sep 2020 08:06:52

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:49', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f726be85-b074-46af-bf12-afe390123eab' User entered '14 Sep 2020 03:06'	System	14 Sep 2020 08:06:52
	System	14 Sep 2020 08:06:52

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 5'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:33:30', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'dfc92a00-840a-4b97-a843-57703a4dabc1' User entered 'None (1)'	System	14 Sep 2020 23:33:55
	System	14 Sep 2020 23:33:55

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:33:38', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'dfc92a00-840a-4b97-a843-57703a4dabc1' User entered 'No (N)'	System	14 Sep 2020 23:33:55
	System	14 Sep 2020 23:33:55

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:33:42', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'dfc92a00-840a-4b97-a843-57703a4dabc1' User entered 'No (N)'	System	14 Sep 2020 23:33:55
	System	14 Sep 2020 23:33:55

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:33:46', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'dfc92a00-840a-4b97-a843-57703a4dabc1' User entered 'None (1)'	System	14 Sep 2020 23:33:55
	System	14 Sep 2020 23:33:55

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:33:52', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'dfc92a00-840a-4b97-a843-57703a4dabc1' User entered '14 Sep 2020 18:33'	System	14 Sep 2020 23:33:55
	System	14 Sep 2020 23:33:55

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 6'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:49:50', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '773bd844-886a-4089-ad6f-2fd8368959e1' User entered 'None (1)'	System	15 Sep 2020 23:50:38
	System	15 Sep 2020 23:50:38

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:49:55', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '773bd844-886a-4089-ad6f-2fd8368959e1' User entered 'No (N)'	System	15 Sep 2020 23:50:38
	System	15 Sep 2020 23:50:38

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:49:58', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '773bd844-886a-4089-ad6f-2fd8368959e1' User entered 'No (N)'	System	15 Sep 2020 23:50:38
	System	15 Sep 2020 23:50:38

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:50:02', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '773bd844-886a-4089-ad6f-2fd8368959e1' User entered 'None (1)'	System	15 Sep 2020 23:50:38
	System	15 Sep 2020 23:50:38

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:50:11', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '773bd844-886a-4089-ad6f-2fd8368959e1' User entered '15 Sep 2020 18:50'	System	15 Sep 2020 23:50:38
	System	15 Sep 2020 23:50:38

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 7'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:34:24', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ba2201e7-3d16-4af3-b407-100b28274aa2' User entered 'None (1)'	System	16 Sep 2020 23:34:55
	System	16 Sep 2020 23:34:55

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:34:28', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ba2201e7-3d16-4af3-b407-100b28274aa2' User entered 'No (N)'	System	16 Sep 2020 23:34:55
	System	16 Sep 2020 23:34:55

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:34:33', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ba2201e7-3d16-4af3-b407-100b28274aa2' User entered 'No (N)'	System	16 Sep 2020 23:34:55
	System	16 Sep 2020 23:34:55

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:34:37', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ba2201e7-3d16-4af3-b407-100b28274aa2' User entered 'None (1)'	System	16 Sep 2020 23:34:55
	System	16 Sep 2020 23:34:55

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:34:48', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ba2201e7-3d16-4af3-b407-100b28274aa2' User entered '16 Sep 2020 18:34'	System	16 Sep 2020 23:34:55
	System	16 Sep 2020 23:34:55

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:31', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '89b82283-9fc1-459f-b624-4191bda40ecc' User entered 'None (0)'	System	10 Sep 2020 17:16:22
	System	10 Sep 2020 17:16:22

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:35', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '89b82283-9fc1-459f-b624-4191bda40ecc' User entered 'None (0)'	System	10 Sep 2020 17:16:22
	System	10 Sep 2020 17:16:22

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:39', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '89b82283-9fc1-459f-b624-4191bda40ecc' User entered 'None (0)'	System	10 Sep 2020 17:16:22
	System	10 Sep 2020 17:16:22

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:44', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '89b82283-9fc1-459f-b624-4191bda40ecc' User entered 'None (0)'	System	10 Sep 2020 17:16:22
	System	10 Sep 2020 17:16:22

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:47', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '89b82283-9fc1-459f-b624-4191bda40ecc' User entered 'None (0)'	System	10 Sep 2020 17:16:22
	System	10 Sep 2020 17:16:22

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:15:56', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '89b82283-9fc1-459f-b624-4191bda40ecc' User entered 'None (0)'	System	10 Sep 2020 17:16:22
	System	10 Sep 2020 17:16:22

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:16:02', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '89b82283-9fc1-459f-b624-4191bda40ecc' User entered 'No (N)'	System	10 Sep 2020 17:16:22
	System	10 Sep 2020 17:16:22

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T12:16:17', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '89b82283-9fc1-459f-b624-4191bda40ecc' User entered '10 Sep 2020 12:16'	System	10 Sep 2020 17:16:22
	System	10 Sep 2020 17:16:22

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '10 Sep 2020 11:31'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '10 Sep 2020 14:01'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:34', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'c7d0a6be-0c78-4d09-8066-c7bfce8f3ffc' User entered 'None (0)'	System	11 Sep 2020 00:28:11
	System	11 Sep 2020 00:28:11

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:36', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'c7d0a6be-0c78-4d09-8066-c7bfce8f3ffc' User entered 'None (0)'	System	11 Sep 2020 00:28:11
	System	11 Sep 2020 00:28:11

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:42', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'c7d0a6be-0c78-4d09-8066-c7bfce8f3ffc' User entered 'None (0)'	System	11 Sep 2020 00:28:11
	System	11 Sep 2020 00:28:11

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:45', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'c7d0a6be-0c78-4d09-8066-c7bfce8f3ffc' User entered 'None (0)'	System	11 Sep 2020 00:28:11
	System	11 Sep 2020 00:28:11

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:48', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'c7d0a6be-0c78-4d09-8066-c7bfce8f3ffc' User entered 'None (0)'	System	11 Sep 2020 00:28:11
	System	11 Sep 2020 00:28:11

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:51', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'c7d0a6be-0c78-4d09-8066-c7bfce8f3ffc' User entered 'None (0)'	System	11 Sep 2020 00:28:11
	System	11 Sep 2020 00:28:11

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:27:57', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'c7d0a6be-0c78-4d09-8066-c7bfce8f3ffc' User entered 'No (N)'	System	11 Sep 2020 00:28:11
	System	11 Sep 2020 00:28:11

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-10T19:28:08', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'c7d0a6be-0c78-4d09-8066-c7bfce8f3ffc' User entered '10 Sep 2020 19:28'	System	11 Sep 2020 00:28:11
	System	11 Sep 2020 00:28:11

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '10 Sep 2020 14:56'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 2'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:04:36', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a62a9136-fac6-4b64-b0fc-f3eefd235592' User entered 'None (0)'	System	11 Sep 2020 23:05:21
	System	11 Sep 2020 23:05:21

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:04:39', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a62a9136-fac6-4b64-b0fc-f3eefd235592' User entered 'None (0)'	System	11 Sep 2020 23:05:21
	System	11 Sep 2020 23:05:21

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:04:42', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a62a9136-fac6-4b64-b0fc-f3eefd235592' User entered 'None (0)'	System	11 Sep 2020 23:05:21
	System	11 Sep 2020 23:05:21

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:04:46', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a62a9136-fac6-4b64-b0fc-f3eefd235592' User entered 'None (0)'	System	11 Sep 2020 23:05:21
	System	11 Sep 2020 23:05:21

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:04:51', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a62a9136-fac6-4b64-b0fc-f3eefd235592' User entered 'None (0)'	System	11 Sep 2020 23:05:21
	System	11 Sep 2020 23:05:21

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:04:55', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a62a9136-fac6-4b64-b0fc-f3eefd235592' User entered 'None (0)'	System	11 Sep 2020 23:05:21
	System	11 Sep 2020 23:05:21

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:05:03', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a62a9136-fac6-4b64-b0fc-f3eefd235592' User entered 'No (N)'	System	11 Sep 2020 23:05:21
	System	11 Sep 2020 23:05:21

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-11T18:05:19', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a62a9136-fac6-4b64-b0fc-f3eefd235592' User entered '11 Sep 2020 18:05'	System	11 Sep 2020 23:05:21
	System	11 Sep 2020 23:05:21

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 3'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:18:56', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2033b161-1d56-4e0f-b1a3-d8bd48dc8f1d' User entered 'None (0)'	System	12 Sep 2020 23:19:49
	System	12 Sep 2020 23:19:49

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:18:59', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2033b161-1d56-4e0f-b1a3-d8bd48dc8f1d' User entered 'None (0)'	System	12 Sep 2020 23:19:49
	System	12 Sep 2020 23:19:49

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:19:06', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2033b161-1d56-4e0f-b1a3-d8bd48dc8f1d' User entered 'None (0)'	System	12 Sep 2020 23:19:49
	System	12 Sep 2020 23:19:49

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:19:12', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2033b161-1d56-4e0f-b1a3-d8bd48dc8f1d' User entered 'None (0)'	System	12 Sep 2020 23:19:49
	System	12 Sep 2020 23:19:49

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:19:15', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2033b161-1d56-4e0f-b1a3-d8bd48dc8f1d' User entered 'None (0)'	System	12 Sep 2020 23:19:49
	System	12 Sep 2020 23:19:49

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:19:18', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2033b161-1d56-4e0f-b1a3-d8bd48dc8f1d' User entered 'None (0)'	System	12 Sep 2020 23:19:49
	System	12 Sep 2020 23:19:49

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:19:38', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2033b161-1d56-4e0f-b1a3-d8bd48dc8f1d' User entered 'No (N)'	System	12 Sep 2020 23:19:49
	System	12 Sep 2020 23:19:49

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-12T18:19:45', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2033b161-1d56-4e0f-b1a3-d8bd48dc8f1d' User entered '12 Sep 2020 18:19'	System	12 Sep 2020 23:19:49
	System	12 Sep 2020 23:19:49

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 4'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:55', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1b481c8b-fe01-45a9-9175-74f1a609463b' User entered 'None (0)'	System	14 Sep 2020 08:07:12
	System	14 Sep 2020 08:07:12

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:56', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1b481c8b-fe01-45a9-9175-74f1a609463b' User entered 'None (0)'	System	14 Sep 2020 08:07:12
	System	14 Sep 2020 08:07:12

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:58', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1b481c8b-fe01-45a9-9175-74f1a609463b' User entered 'None (0)'	System	14 Sep 2020 08:07:12
	System	14 Sep 2020 08:07:12

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:06:59', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1b481c8b-fe01-45a9-9175-74f1a609463b' User entered 'None (0)'	System	14 Sep 2020 08:07:12
	System	14 Sep 2020 08:07:12

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:07:01', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1b481c8b-fe01-45a9-9175-74f1a609463b' User entered 'None (0)'	System	14 Sep 2020 08:07:12
	System	14 Sep 2020 08:07:12

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:07:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1b481c8b-fe01-45a9-9175-74f1a609463b' User entered 'None (0)'	System	14 Sep 2020 08:07:12
	System	14 Sep 2020 08:07:12

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:07:06', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1b481c8b-fe01-45a9-9175-74f1a609463b' User entered 'No (N)'	System	14 Sep 2020 08:07:12
	System	14 Sep 2020 08:07:12

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T03:07:09', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1b481c8b-fe01-45a9-9175-74f1a609463b' User entered '14 Sep 2020 03:07'	System	14 Sep 2020 08:07:12
	System	14 Sep 2020 08:07:12

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 5'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:33:58', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '063c842d-e447-4a4a-b5e6-eb63cff55047' User entered 'None (0)'	System	14 Sep 2020 23:34:43
	System	14 Sep 2020 23:34:43

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:34:02', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '063c842d-e447-4a4a-b5e6-eb63cff55047' User entered 'None (0)'	System	14 Sep 2020 23:34:43
	System	14 Sep 2020 23:34:43

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:34:06', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '063c842d-e447-4a4a-b5e6-eb63cff55047' User entered 'None (0)'	System	14 Sep 2020 23:34:43
	System	14 Sep 2020 23:34:43

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:34:11', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '063c842d-e447-4a4a-b5e6-eb63cff55047' User entered 'None (0)'	System	14 Sep 2020 23:34:43
	System	14 Sep 2020 23:34:43

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:34:15', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '063c842d-e447-4a4a-b5e6-eb63cff55047' User entered 'None (0)'	System	14 Sep 2020 23:34:43
	System	14 Sep 2020 23:34:43

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:34:18', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '063c842d-e447-4a4a-b5e6-eb63cff55047' User entered 'None (0)'	System	14 Sep 2020 23:34:43
	System	14 Sep 2020 23:34:43

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:34:31', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '063c842d-e447-4a4a-b5e6-eb63cff55047' User entered 'No (N)'	System	14 Sep 2020 23:34:43
	System	14 Sep 2020 23:34:43

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-14T18:34:41', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '063c842d-e447-4a4a-b5e6-eb63cff55047' User entered '14 Sep 2020 18:34'	System	14 Sep 2020 23:34:43
	System	14 Sep 2020 23:34:43

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 6'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:50:17', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '443dec38-58f6-4b2f-a9ff-f92933307f98' User entered 'None (0)'	System	15 Sep 2020 23:51:00
	System	15 Sep 2020 23:51:00

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:50:20', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '443dec38-58f6-4b2f-a9ff-f92933307f98' User entered 'None (0)'	System	15 Sep 2020 23:51:00
	System	15 Sep 2020 23:51:00

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:50:22', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '443dec38-58f6-4b2f-a9ff-f92933307f98' User entered 'None (0)'	System	15 Sep 2020 23:51:00
	System	15 Sep 2020 23:51:00

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:50:36', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '443dec38-58f6-4b2f-a9ff-f92933307f98' User entered 'None (0)'	System	15 Sep 2020 23:51:00
	System	15 Sep 2020 23:51:00

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:50:38', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '443dec38-58f6-4b2f-a9ff-f92933307f98' User entered 'None (0)'	System	15 Sep 2020 23:51:00
	System	15 Sep 2020 23:51:00

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:50:40', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '443dec38-58f6-4b2f-a9ff-f92933307f98' User entered 'None (0)'	System	15 Sep 2020 23:51:00
	System	15 Sep 2020 23:51:00

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:50:46', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '443dec38-58f6-4b2f-a9ff-f92933307f98' User entered 'No (N)'	System	15 Sep 2020 23:51:00
	System	15 Sep 2020 23:51:00

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-15T18:50:55', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '443dec38-58f6-4b2f-a9ff-f92933307f98' User entered '15 Sep 2020 18:50'	System	15 Sep 2020 23:51:00
	System	15 Sep 2020 23:51:00

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	10 Sep 2020 16:52:32
User entered 'Day 7'	System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:34:53', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'db755570-b136-45a2-8028-a66a754dc6d3' User entered 'None (0)'	System	16 Sep 2020 23:35:58
	System	16 Sep 2020 23:35:58

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:34:57', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'db755570-b136-45a2-8028-a66a754dc6d3' User entered 'None (0)'	System	16 Sep 2020 23:35:58
	System	16 Sep 2020 23:35:58

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:35:03', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'db755570-b136-45a2-8028-a66a754dc6d3' User entered 'None (0)'	System	16 Sep 2020 23:35:58
	System	16 Sep 2020 23:35:58

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:35:10', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'db755570-b136-45a2-8028-a66a754dc6d3' User entered 'None (0)'	System	16 Sep 2020 23:35:58
	System	16 Sep 2020 23:35:58

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:35:13', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'db755570-b136-45a2-8028-a66a754dc6d3' User entered 'None (0)'	System	16 Sep 2020 23:35:58
	System	16 Sep 2020 23:35:58

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:35:16', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'db755570-b136-45a2-8028-a66a754dc6d3' User entered 'None (0)'	System	16 Sep 2020 23:35:58
	System	16 Sep 2020 23:35:58

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:35:42', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'db755570-b136-45a2-8028-a66a754dc6d3' User entered 'No (N)'	System	16 Sep 2020 23:35:58
	System	16 Sep 2020 23:35:58

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-09-16T18:35:52', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'db755570-b136-45a2-8028-a66a754dc6d3' User entered '16 Sep 2020 18:35'	System	16 Sep 2020 23:35:58
	System	16 Sep 2020 23:35:58

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:52:32

US3012131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	21 Sep 2020 22:21:29
	(b) (4)	

US3012131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:30
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 06:44:43
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as entered' (Site from System).	Katherine Davis (b) (4) (b) (4)	21 Sep 2020 22:21:43
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Sep 2020 22:21:29
User entered '21 Sep 2020'	Katherine Davis (b) (4) (b) (4)	21 Sep 2020 22:21:29

US3012131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Katherine Davis (b) (4)	21 Sep 2020 22:21:29
	(b) (4)	

US3012131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	21 Sep 2020 22:21:29
	(b) (4)	

US3012131

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	21 Sep 2020 22:21:49
	(b) (4)	

US3012131

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'I'	(b) (4), (b) (6) System	21 Sep 2020 22:21:49

US3012131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:30
User entered 'Yes (Y)'	(b) (4) Tambra Dora (b) (4) (b) (4)	24 Sep 2020 22:12:07

US3012131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered '24 Sep 2020'	Tambra Dora (b) (4)	24 Sep 2020 22:12:07
	(b) (4)	

US3012131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	24 Sep 2020 22:12:07
	(b) (4)	

US3012131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered empty.	Tambra Dora (b) (4)	24 Sep 2020 22:12:07
	(b) (4)	

US3012131

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Yes (Y)'	Tambra Dora (b) (4)	24 Sep 2020 22:12:10
	(b) (4)	

US3012131

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 22:12:10

US3012131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Yes (Y)'	Tambra Dora (b) (4)	01 Oct 2020 23:21:09
	(b) (4)	

US3012131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered '1 Oct 2020'	Tambra Dora (b) (4)	01 Oct 2020 23:21:09
	(b) (4)	

US3012131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4)	01 Oct 2020 23:21:09
	(b) (4)	

US3012131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered empty.	Tambra Dora (b) (4)	01 Oct 2020 23:21:09
	(b) (4)	

US3012131

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:30
	(b) (4)	
User entered 'Yes (Y)'	Tambra Dora (b) (4)	01 Oct 2020 23:21:13
	(b) (4)	

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Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'I'	(b) (4), (b) (6) System	01 Oct 2020 23:21:13

US3012131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	14 Oct 2020 17:11:53
	(b) (4)	

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Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '14 Oct 2020'	Katherine Davis (b) (4)	14 Oct 2020 17:11:53
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Clinic (Clinic)'	Katherine Davis (b) (4)	14 Oct 2020 17:11:53
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'VISIT3'	(b) (4), (b) (6) System	14 Oct 2020 17:11:53

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	14 Oct 2020 17:12:34
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '14 Oct 2020'	Katherine Davis (b) (4)	14 Oct 2020 17:12:34
	(b) (4)	

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Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '10:20'	Katherine Davis (b) (4)	14 Oct 2020 17:12:34
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '14 Oct 2020 10:20'	(b) (4), (b) (6) System	14 Oct 2020 17:12:34

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '98.2' F	Katherine Davis (b) (4)	14 Oct 2020 17:12:34
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Oral (Oral)'	Katherine Davis (b) (4)	14 Oct 2020 17:12:34
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	14 Oct 2020 17:12:34
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '72'	Katherine Davis (b) (4)	14 Oct 2020 17:12:34
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'bpm'	(b) (4), (b) (6) System	14 Oct 2020 17:12:34

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '14'	Katherine Davis (b) (4)	14 Oct 2020 17:12:34
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Oct 2020 17:12:34

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Feb 2021 20:26:51
User entered '123'	(b) (4) Katherine Davis (b) (4) (b) (4)	14 Oct 2020 17:12:34

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'mmHg'	(b) (4), (b) (6) System	14 Oct 2020 17:12:34

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '74'	Katherine Davis (b) (4)	14 Oct 2020 17:12:34
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'mmHg'	(b) (4), (b) (6) System	14 Oct 2020 17:12:34

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 17:11:11

US3012131

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'No (N)'	Katherine Davis (b) (4)	14 Oct 2020 17:12:44
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered empty.	Katherine Davis (b) (4)	14 Oct 2020 17:12:44
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	14 Oct 2020 17:13:01
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '14 Oct 2020'	Katherine Davis (b) (4)	14 Oct 2020 17:13:01
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered '10:39'	Katherine Davis (b) (4)	14 Oct 2020 17:13:01
	(b) (4)	

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Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered '14 Oct 2020 10:39'	(b) (4), (b) (6) System	14 Oct 2020 17:13:01

US3012131

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	12 Feb 2021 20:26:51
	(b) (4)	
User entered 'Yes (Y)'	Katherine Davis (b) (4)	14 Oct 2020 17:13:07
	(b) (4)	

US3012131

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'I'	(b) (4), (b) (6) System	14 Oct 2020 17:13:07

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47
Data entry locked.	System	13 Aug 2020 22:16:58
User entered 'Day 64'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47
Data entry locked.	System	13 Aug 2020 22:16:58
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47
Data entry locked.	System	13 Aug 2020 22:16:58
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 71'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-10-23T17:58:56', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '314bedde-300f-46fb-b48d-4876ee2c21d9' User entered 'No (N)'	System	23 Oct 2020 22:59:21
	System	23 Oct 2020 22:59:21

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-10-23T17:59:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '314bedde-300f-46fb-b48d-4876ee2c21d9' User entered 'No (N)'	System	23 Oct 2020 22:59:21
	System	23 Oct 2020 22:59:21

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-10-23T17:59:15', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '314bedde-300f-46fb-b48d-4876ee2c21d9' User entered '23 Oct 2020 17:59:15'	System	23 Oct 2020 22:59:21
	System	23 Oct 2020 22:59:21

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 78'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-10-29T19:26:44', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '5bd86d64-15c4-4d9a-bb2b-8c550a74bc62' User entered 'No (N)'	System	30 Oct 2020 00:26:54
	System	30 Oct 2020 00:26:54

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-10-29T19:26:46', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '5bd86d64-15c4-4d9a-bb2b-8c550a74bc62' User entered 'No (N)'	System	30 Oct 2020 00:26:54
	System	30 Oct 2020 00:26:54

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-10-29T19:26:51', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '5bd86d64-15c4-4d9a-bb2b-8c550a74bc62' User entered '29 Oct 2020 19:26:51'	System	30 Oct 2020 00:26:54
	System	30 Oct 2020 00:26:54

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered 'Day 92'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-11-12T20:30:26', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '841594a0-0a94-4574-8d5e-43cca5b38a8d' User entered 'No (N)'	System	13 Nov 2020 02:31:36
	System	13 Nov 2020 02:31:36

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-11-12T20:31:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '841594a0-0a94-4574-8d5e-43cca5b38a8d' User entered 'No (N)'	System	13 Nov 2020 02:31:36
	System	13 Nov 2020 02:31:36

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-11-12T20:31:32', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '841594a0-0a94-4574-8d5e-43cca5b38a8d' User entered '12 Nov 2020 20:31:32'	System	13 Nov 2020 02:31:36
	System	13 Nov 2020 02:31:36

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 09:30:40
Data entry locked.	(b) (4), (b) (6) System	13 Aug 2020 22:16:58
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47
Data entry locked.	System	13 Aug 2020 22:16:58
User entered 'Day 99'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please 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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please 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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47
Data entry locked.	System	13 Aug 2020 22:16:58
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 22:16:58

US3012131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:37:47
Data entry locked.	System	13 Aug 2020 22:16:58
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 22:16:58

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-11-21T12:51:11', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd0fba99c-8d78-4a73-99a8-d6a7567a9b33'	System	21 Nov 2020 18:51:36
User entered 'No (N)'	System	21 Nov 2020 18:51:36

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-11-21T12:51:15', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd0fba99c-8d78-4a73-99a8-d6a7567a9b33'	System	21 Nov 2020 18:51:36
User entered 'No (N)'	System	21 Nov 2020 18:51:36

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-11-21T12:51:32', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd0fba99c-8d78-4a73-99a8-d6a7567a9b33' User entered '21 Nov 2020 12:51:32'	System	21 Nov 2020 18:51:36
	System	21 Nov 2020 18:51:36

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-11-28T18:49:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '90ed6223-50f1-48f1-9d01-0e2dc7ce9475'	System	29 Nov 2020 00:49:30
User entered 'No (N)'	System	29 Nov 2020 00:49:30

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-11-28T18:49:09', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '90ed6223-50f1-48f1-9d01-0e2dc7ce9475'	System	29 Nov 2020 00:49:30
User entered 'No (N)'	System	29 Nov 2020 00:49:30

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-11-28T18:49:20', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '90ed6223-50f1-48f1-9d01-0e2dc7ce9475'	System	29 Nov 2020 00:49:30
User entered '28 Nov 2020 18:49:20'	System	29 Nov 2020 00:49:30

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-05T17:40:16', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '333aaaa3-7921-40d4-9874-8ec5cb49a515'	System	05 Dec 2020 23:40:34
User entered 'No (N)'	System	05 Dec 2020 23:40:34

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-05T17:40:20', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '333aaaa3-7921-40d4-9874-8ec5cb49a515' User entered 'No (N)'	System	05 Dec 2020 23:40:34
	System	05 Dec 2020 23:40:34

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-05T17:40:30', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '333aaaa3-7921-40d4-9874-8ec5cb49a515' User entered '05 Dec 2020 17:40:30'	System	05 Dec 2020 23:40:34
	System	05 Dec 2020 23:40:34

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-13T12:34:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2085e001-8c05-411c-8258-6c7df559dd69'	System	13 Dec 2020 18:34:57
User entered 'Yes (Y)'	System	13 Dec 2020 18:34:57

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-13T12:34:25', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2085e001-8c05-411c-8258-6c7df559dd69'	System	13 Dec 2020 18:34:57
User entered 'No (N)'	System	13 Dec 2020 18:34:57

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-13T12:34:30', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2085e001-8c05-411c-8258-6c7df559dd69'	System	13 Dec 2020 18:34:57
User entered 'No (N)'	System	13 Dec 2020 18:34:57

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-13T12:34:35', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2085e001-8c05-411c-8258-6c7df559dd69'	System	13 Dec 2020 18:34:57
User entered 'Yes (Y)'	System	13 Dec 2020 18:34:57

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-13T12:34:38', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2085e001-8c05-411c-8258-6c7df559dd69'	System	13 Dec 2020 18:34:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 18:34:57

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-13T12:34:45', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2085e001-8c05-411c-8258-6c7df559dd69' User entered '13 Dec 2020 12:34:45'	System	13 Dec 2020 18:34:57
	System	13 Dec 2020 18:34:57

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-20T16:23:33', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '819a2952-5b0e-4709-bf18-f5b8cc3852fd' User entered 'No (N)'	System	20 Dec 2020 22:23:51
	System	20 Dec 2020 22:23:51

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-20T16:23:24', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '819a2952-5b0e-4709-bf18-f5b8cc3852fd' User entered 'No (N)'	System	20 Dec 2020 22:23:51
	System	20 Dec 2020 22:23:51

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-20T16:23:44', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '819a2952-5b0e-4709-bf18-f5b8cc3852fd' User entered '20 Dec 2020 16:23:44'	System	20 Dec 2020 22:23:51
	System	20 Dec 2020 22:23:51

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-27T09:09:31', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f7b5003a-27b4-46c7-94e4-79663fb14244' User entered 'No (N)'	System	27 Dec 2020 15:10:15
	System	27 Dec 2020 15:10:15

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-27T09:10:04', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f7b5003a-27b4-46c7-94e4-79663fb14244' User entered 'No (N)'	System	27 Dec 2020 15:10:15
	System	27 Dec 2020 15:10:15

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2020-12-27T09:10:10', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'f7b5003a-27b4-46c7-94e4-79663fb14244' User entered '27 Dec 2020 09:10:10'	System	27 Dec 2020 15:10:15
	System	27 Dec 2020 15:10:15

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-03T08:42:08', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1113a2c2-ddc4-4fa4-905a-e38e4eec431f' User entered 'No (N)'	System	03 Jan 2021 14:42:18
	System	03 Jan 2021 14:42:18

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-03T08:42:10', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1113a2c2-ddc4-4fa4-905a-e38e4eec431f' User entered 'No (N)'	System	03 Jan 2021 14:42:18
	System	03 Jan 2021 14:42:18

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-03T08:42:14', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '1113a2c2-ddc4-4fa4-905a-e38e4eec431f' User entered '03 Jan 2021 08:42:14'	System	03 Jan 2021 14:42:18
	System	03 Jan 2021 14:42:18

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-10T17:51:07', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '36410e43-c0a9-443b-9ea3-2109e5e5320f' User entered 'No (N)'	System	10 Jan 2021 23:51:25
	System	10 Jan 2021 23:51:25

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-10T17:51:12', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '36410e43-c0a9-443b-9ea3-2109e5e5320f' User entered 'No (N)'	System	10 Jan 2021 23:51:25
	System	10 Jan 2021 23:51:25

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-10T17:51:19', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '36410e43-c0a9-443b-9ea3-2109e5e5320f' User entered '10 Jan 2021 17:51:19'	System	10 Jan 2021 23:51:25
	System	10 Jan 2021 23:51:25

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-18T12:38:35', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'bb862cd7-1c1b-4a0a-ba07-7dabe324403c' User entered 'No (N)'	System	18 Jan 2021 18:38:43
	System	18 Jan 2021 18:38:43

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-18T12:38:37', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'bb862cd7-1c1b-4a0a-ba07-7dabe324403c'	System	18 Jan 2021 18:38:43
User entered 'No (N)'	System	18 Jan 2021 18:38:43

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-18T12:38:40', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'bb862cd7-1c1b-4a0a-ba07-7dabe324403c' User entered '18 Jan 2021 12:38:40'	System	18 Jan 2021 18:38:43
	System	18 Jan 2021 18:38:43

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-24T19:25:43', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2c30e292-1f49-407e-a70d-f8c67216691e' User entered 'No (N)'	System	25 Jan 2021 01:26:01
	System	25 Jan 2021 01:26:01

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-24T19:25:48', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2c30e292-1f49-407e-a70d-f8c67216691e' User entered 'No (N)'	System	25 Jan 2021 01:26:01

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-24T19:25:58', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2c30e292-1f49-407e-a70d-f8c67216691e' User entered '24 Jan 2021 19:25:58'	System	25 Jan 2021 01:26:01

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-31T08:48:58', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd5032e4d-4856-40a9-b1a3-db7377baba2e' User entered 'No (N)'	System	31 Jan 2021 14:49:15
	System	31 Jan 2021 14:49:15

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-31T08:49:03', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd5032e4d-4856-40a9-b1a3-db7377baba2e' User entered 'No (N)'	System	31 Jan 2021 14:49:15
	System	31 Jan 2021 14:49:15

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-01-31T08:49:13', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd5032e4d-4856-40a9-b1a3-db7377baba2e' User entered '31 Jan 2021 08:49:13'	System	31 Jan 2021 14:49:15
	System	31 Jan 2021 14:49:15

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-02-06T18:33:29', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '81188f74-340a-4dc1-91c0-107141894c37'	System	07 Feb 2021 00:33:47
User entered 'No (N)'	System	07 Feb 2021 00:33:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-02-06T18:33:34', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '81188f74-340a-4dc1-91c0-107141894c37'	System	07 Feb 2021 00:33:47
User entered 'No (N)'	System	07 Feb 2021 00:33:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-02-06T18:33:42', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '81188f74-340a-4dc1-91c0-107141894c37' User entered '06 Feb 2021 18:33:42'	System	07 Feb 2021 00:33:47
	System	07 Feb 2021 00:33:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-02-14T19:17:05', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ba8aef9c-085c-458d-914e-fcf3eeade3f0'	System	15 Feb 2021 01:17:19
User entered 'No (N)'	System	15 Feb 2021 01:17:19

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-02-14T19:17:09', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ba8aef9c-085c-458d-914e-fcf3eeade3f0'	System	15 Feb 2021 01:17:19
User entered 'No (N)'	System	15 Feb 2021 01:17:19

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-02-14T19:17:17', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'ba8aef9c-085c-458d-914e-fcf3eeade3f0' User entered '14 Feb 2021 19:17:17'	System	15 Feb 2021 01:17:19
	System	15 Feb 2021 01:17:19

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-02-22T21:21:41-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b7a2a544-b1ee-4c2e-8b36-b63a24acf3f6'	System	23 Feb 2021 03:21:57
User entered 'No (N)'	System	23 Feb 2021 03:21:57

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-02-22T21:21:45-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b7a2a544-b1ee-4c2e-8b36-b63a24acf3f6'	System	23 Feb 2021 03:21:57
User entered 'No (N)'	System	23 Feb 2021 03:21:57

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-02-22T21:21:53-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b7a2a544-b1ee-4c2e-8b36-b63a24acf3f6'	System	23 Feb 2021 03:21:57
User entered '23 Feb 2021 03:21:53'	System	23 Feb 2021 03:21:57

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-03T10:09:05-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '47102e62-cced-4f5e-bb14-7994a83a90cb' User entered 'No (N)'	System	03 Mar 2021 16:09:28
	System	03 Mar 2021 16:09:28

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-03T10:09:08-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '47102e62-cced-4f5e-bb14-7994a83a90cb'	System	03 Mar 2021 16:09:28
User entered 'No (N)'	System	03 Mar 2021 16:09:28

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-03T10:09:26-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '47102e62-cced-4f5e-bb14-7994a83a90cb'	System	03 Mar 2021 16:09:28
User entered '03 Mar 2021 16:09:26'	System	03 Mar 2021 16:09:28

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-07T18:10:31-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '67c09fcf-a559-449b-be8a-2a43c6977c0b'	System	10 Mar 2021 21:44:49
User entered 'No (N)'	System	10 Mar 2021 21:44:49

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-07T18:10:37-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '67c09fcf-a559-449b-be8a-2a43c6977c0b'	System	10 Mar 2021 21:44:49
User entered 'No (N)'	System	10 Mar 2021 21:44:49

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-07T18:10:46-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '67c09fcf-a559-449b-be8a-2a43c6977c0b' User entered '08 Mar 2021 00:10:46'	System	10 Mar 2021 21:44:49

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-17T13:13:17-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a2a05b8b-0a0d-42ef-acbc-996ea0d5088f'	System	17 Mar 2021 18:13:36
User entered 'No (N)'	System	17 Mar 2021 18:13:36

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-17T13:13:24-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a2a05b8b-0a0d-42ef-acbc-996ea0d5088f'	System	17 Mar 2021 18:13:36
User entered 'No (N)'	System	17 Mar 2021 18:13:36

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-17T13:13:30-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'a2a05b8b-0a0d-42ef-acbc-996ea0d5088f'	System	17 Mar 2021 18:13:36
User entered '17 Mar 2021 13:13:30'	System	17 Mar 2021 18:13:36

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-21T17:23:45-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'bf40cde6-bcb6-4beb-ac41-2246ddf76070'	System	21 Mar 2021 22:24:00
User entered 'No (N)'	System	21 Mar 2021 22:24:00

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-21T17:23:51-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'bf40cde6-bcb6-4beb-ac41-2246ddf76070'	System	21 Mar 2021 22:24:00
User entered 'No (N)'	System	21 Mar 2021 22:24:00

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-21T17:23:58-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'bf40cde6-bcb6-4beb-ac41-2246ddf76070' User entered '21 Mar 2021 17:23:58'	System	21 Mar 2021 22:24:00
	System	21 Mar 2021 22:24:00

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-29T11:02:18-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'aff1991e-550b-484f-a94f-e0eecd8b2d38'	System	29 Mar 2021 16:08:36
User entered 'No (N)'	System	29 Mar 2021 16:08:36

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-29T11:02:21-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'aff1991e-550b-484f-a94f-e0eecd8b2d38'	System	29 Mar 2021 16:08:36
User entered 'No (N)'	System	29 Mar 2021 16:08:36

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-29T11:02:31-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'aff1991e-550b-484f-a94f-e0eecd8b2d38'	System	29 Mar 2021 16:08:36
User entered '29 Mar 2021 11:02:31'	System	29 Mar 2021 16:08:36

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-05T07:58:30-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '8b376587-2659-436b-8c61-f2d534bbb061'	System	05 Apr 2021 12:58:51
User entered 'No (N)'	System	05 Apr 2021 12:58:51

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-05T07:58:35-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '8b376587-2659-436b-8c61-f2d534bbb061'	System	05 Apr 2021 12:58:51
User entered 'No (N)'	System	05 Apr 2021 12:58:51

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-05T07:58:45-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '8b376587-2659-436b-8c61-f2d534bbb061'	System	05 Apr 2021 12:58:51
User entered '05 Apr 2021 07:58:45'	System	05 Apr 2021 12:58:51

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-11T19:03:15-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd02fbbf1-5760-491b-a535-cc22b40f59d3'	System	12 Apr 2021 00:03:30
User entered 'No (N)'	System	12 Apr 2021 00:03:30

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-11T19:03:20-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd02fbbf1-5760-491b-a535-cc22b40f59d3'	System	12 Apr 2021 00:03:30
User entered 'No (N)'	System	12 Apr 2021 00:03:30

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-11T19:03:28-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'd02fbbf1-5760-491b-a535-cc22b40f59d3'	System	12 Apr 2021 00:03:30
User entered '11 Apr 2021 19:03:28'	System	12 Apr 2021 00:03:30

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-19T16:22:50-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '14a97a5f-7352-47db-b289-4104178e0e4a'	System	19 Apr 2021 21:23:47
User entered 'No (N)'	System	19 Apr 2021 21:23:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-19T16:23:28-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '14a97a5f-7352-47db-b289-4104178e0e4a'	System	19 Apr 2021 21:23:47
User entered 'No (N)'	System	19 Apr 2021 21:23:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-19T16:23:43-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '14a97a5f-7352-47db-b289-4104178e0e4a' User entered '19 Apr 2021 16:23:43'	System	19 Apr 2021 21:23:47
	System	19 Apr 2021 21:23:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-26T11:50:24-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b296b8d8-f3a7-4ea2-b763-6f0e6773b769'	System	26 Apr 2021 16:50:47
User entered 'No (N)'	System	26 Apr 2021 16:50:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-26T11:50:37-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b296b8d8-f3a7-4ea2-b763-6f0e6773b769'	System	26 Apr 2021 16:50:47
User entered 'No (N)'	System	26 Apr 2021 16:50:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-04-26T11:50:45-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'b296b8d8-f3a7-4ea2-b763-6f0e6773b769'	System	26 Apr 2021 16:50:47
User entered '26 Apr 2021 11:50:45'	System	26 Apr 2021 16:50:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-05-02T18:19:11-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2be6ba46-51e7-4015-b060-ed91c8fe08c7'	System	02 May 2021 23:19:26
User entered 'No (N)'	System	02 May 2021 23:19:26

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-05-02T18:19:16-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2be6ba46-51e7-4015-b060-ed91c8fe08c7'	System	02 May 2021 23:19:26
User entered 'No (N)'	System	02 May 2021 23:19:26

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-05-02T18:19:23-05:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: '2be6ba46-51e7-4015-b060-ed91c8fe08c7'	System	02 May 2021 23:19:26
User entered '02 May 2021 18:19:23'	System	02 May 2021 23:19:26

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:37:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:37:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:37:47

US3012131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:37:47
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:37:47

US3012131

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:46:53

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) (b) (4), (b) (6)	24 Apr 2021 07:23:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-07T18:11:02-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'e4888613-1ecb-44a8-a812-3a2fd8b9a592'	System	10 Mar 2021 21:44:49
User entered 'No (N)'	System	10 Mar 2021 21:44:49

US3012131

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:46:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 07:23:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (138ABA7B-7471-42F0-879B-2E00E4330077)', Time: '2021-03-07T18:11:08-06:00', User OID: 'PatientReportedOutcome (US3012131)', ODM File OID: 'e4888613-1ecb-44a8-a812-3a2fd8b9a592' User entered '08 Mar 2021 00:11:08'	System	10 Mar 2021 21:44:49
	System	10 Mar 2021 21:44:49

US3012131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:27:27
	(b) (4)	
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	05 Nov 2020 20:01:24
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:27:27
	(b) (4)	
User entered '05 Nov 2020'	Pamela Fidler (b) (4)	05 Nov 2020 20:01:24
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:27:27
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Pamela Fidler (b) (4)	05 Nov 2020 20:01:24
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:27:27
	(b) (4)	
User entered empty.	Pamela Fidler (b) (4)	05 Nov 2020 20:01:24
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:27:27
	(b) (4)	
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	05 Nov 2020 20:01:28
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:11
User entered 'I'	(b) (4), (b) (6) System	05 Nov 2020 20:01:28

US3012131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Jan 2021 21:07:01
User entered 'Yes (Y)'	(b) (4), (b) (6) Pamela Fidler (b) (4)	09 Dec 2020 22:44:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Jan 2021 21:07:01
User entered '09 Dec 2020'	(b) (4), (b) (6) Pamela Fidler (b) (4)	09 Dec 2020 22:44:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Jan 2021 21:07:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) Pamela Fidler (b) (4)	09 Dec 2020 22:44:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Jan 2021 21:07:01
User entered empty.	(b) (4), (b) (6) Pamela Fidler (b) (4)	09 Dec 2020 22:44:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Jan 2021 21:07:05
User entered 'Yes (Y)'	(b) (4), (b) (6) Pamela Fidler (b) (4)	09 Dec 2020 22:44:37
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User entered 'I'	(b) (4), (b) (6) System	09 Dec 2020 22:44:37

US3012131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Dean Skiles (b) (4) (b) (4)	08 Jan 2021 23:49:51

US3012131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '8 Jan 2021'	(b) (4) Dean Skiles (b) (4)	08 Jan 2021 23:49:51
	(b) (4)	

US3012131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dean Skiles (b) (4)	08 Jan 2021 23:49:51
	(b) (4)	

US3012131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Dean Skiles (b) (4)	08 Jan 2021 23:49:51
	(b) (4)	

US3012131

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Dean Skiles (b) (4)	08 Jan 2021 23:50:01
	(b) (4)	

US3012131

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User entered 'I'	(b) (4), (b) (6) System	08 Jan 2021 23:50:01

US3012131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	10 Mar 2021 20:43:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '05 Feb 2021'	(b) (4) Pamela Fidler (b) (4)	10 Mar 2021 20:43:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Pamela Fidler (b) (4)	10 Mar 2021 20:43:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Pamela Fidler (b) (4)	10 Mar 2021 20:43:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	10 Mar 2021 20:43:51
	(b) (4)	
	(b) (4)	

US3012131

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 07:55:37
User entered 'I'	(b) (4), (b) (6) System	10 Mar 2021 20:43:51

US3012131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. '(Site from DM). Query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'Updated' (Site from DM). User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. '(Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) Pamela Fidler (b) (4) (b) (4) (b) (4)	31 Mar 2021 18:42:42
User entered 'Yes (Y)'	Laurence Chu (b) (4) (b) (4) Pamela Fidler (b) (4) (b) (4) (b) (4)	29 Mar 2021 21:11:56
		29 Mar 2021 17:49:07
		26 Mar 2021 00:52:46
		10 Mar 2021 21:55:49

US3012131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '10 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	10 Mar 2021 21:55:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Clinic (Clinic)'	(b) (4) Pamela Fidler (b) (4)	10 Mar 2021 21:55:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User entered 'VISIT4'	(b) (4), (b) (6) System	10 Mar 2021 21:55:49

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 21:11:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered '10 Mar 2021'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 21:11:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs time of assessment on Visit 4 Day 209 is 10:20 and on OL D-57 is 10:30. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:01:57
Query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs time of assessment on Visit 4 Day 209 is 10:20 and on OL D-57 is 10:30. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'Corrected' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	01 Apr 2021 21:34:25
User entered '10:30' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	01 Apr 2021 21:34:10
User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs time of assessment on Visit 4 Day 209 is 10:20 and on OL D-57 is 10:30. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	31 Mar 2021 18:46:03
User entered '10:20'	Pamela Fidler (b) (4) (b) (4) (b) (4)	29 Mar 2021 21:11:49

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User entered '10 Mar 2021 10:30'	(b) (4), (b) (6) System	01 Apr 2021 21:34:10
User entered '10 Mar 2021 10:20'	System	29 Mar 2021 21:11:49

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered '98.8' F	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 21:11:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered 'Oral (Oral)'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 21:11:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered empty.	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 21:11:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	29 Mar 2021 21:12:05
User entered '71' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4) (b) (4)	29 Mar 2021 21:12:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Mar 2021 21:11:49
User entered '98.' (non-conformant).	Pamela Fidler (b) (4) (b) (4) (b) (4)	29 Mar 2021 21:11:49

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User entered 'bpm'	(b) (4), (b) (6) System	29 Mar 2021 21:12:05
User entered empty.	System	29 Mar 2021 21:11:49

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered '16'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 21:11:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User entered 'breaths/min'	(b) (4), (b) (6) System	29 Mar 2021 21:11:49

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered '108'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 21:11:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User entered 'mmHg'	(b) (4), (b) (6) System	29 Mar 2021 21:11:49

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered '72'	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 21:11:49
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User entered 'mmHg'	(b) (4), (b) (6) System	29 Mar 2021 21:11:49

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	(b) (4), (b) (6) 27 Apr 2021 17:05:04

US3012131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	(b) (4), (b) (6) 27 Apr 2021 17:05:04

US3012131

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	10 Mar 2021 21:55:52
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Pamela Fidler (b) (4)	10 Mar 2021 21:55:52
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	08 Apr 2021 14:52:06
User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however immunogenicity assessment performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	31 Mar 2021 18:42:33
Query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however immunogenicity assessment performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4) (b) (4) (b) (4)	29 Mar 2021 21:11:27
Signature has been broken.	Pamela Fidler (b) (4) (b) (4) (b) (4)	29 Mar 2021 21:11:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4) (b) (4)	29 Mar 2021 21:11:22
User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however immunogenicity assessment performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 17:49:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	10 Mar 2021 21:55:54

US3012131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
Signature has been broken.	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 21:11:22
	(b) (4)	
	(b) (4)	
User entered '10 Mar 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Mar 2021 21:11:22
	(b) (4)	
	(b) (4)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Pamela Fidler (b) (4)	10 Mar 2021 21:55:54
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
Signature has been broken.	(b) (4) Pamela Fidler (b) (4)	29 Mar 2021 21:11:22
	(b) (4)	
	(b) (4)	
User entered '10:39' reason for change: Data Entry Error	Pamela Fidler (b) (4)	29 Mar 2021 21:11:22
	(b) (4)	
	(b) (4)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Pamela Fidler (b) (4)	10 Mar 2021 21:55:54
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User entered '10 Mar 2021 10:39'	(b) (4), (b) (6) System	29 Mar 2021 21:11:22
User entered empty.	System	10 Mar 2021 21:55:54

US3012131

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	10 Mar 2021 21:55:56
	(b) (4)	
	(b) (4)	

US3012131

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 17:05:04
User entered 'I'	(b) (4), (b) (6) System	10 Mar 2021 21:55:56

US3012131

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 20:10:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	05 Apr 2021 16:22:01
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	

US3012131

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 20:10:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	05 Apr 2021 16:22:01
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	

US3012131

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 20:10:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	05 Apr 2021 16:22:01

US3012131

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 20:10:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	05 Apr 2021 16:22:01
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 20:10:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	08 Apr 2021 14:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	05 Apr 2021 16:22:05

US3012131

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 20:10:04
User entered 'I'	(b) (4), (b) (6) System	05 Apr 2021 16:22:05

US3012131

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

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Dean Skiles (b) (4)	08 Jan 2021 23:51:21
	(b) (4)	

US3012131

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

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '8 Jan 2021'	Dean Skiles (b) (4)	08 Jan 2021 23:51:21
	(b) (4)	

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

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[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 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Clinic (Clinic)'	Dean Skiles (b) (4)	08 Jan 2021 23:51:21
	(b) (4)	

US3012131

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

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 23:51:21

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '8 Jan 2021'	Dean Skiles (b) (4)	08 Jan 2021 23:52:15
	(b) (4)	

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[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 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:54:38

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Dean Skiles (b) (4)	08 Jan 2021 23:52:15
	(b) (4)	

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:54:38

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '8 Jan 2021'	Dean Skiles (b) (4)	08 Jan 2021 23:52:15
	(b) (4)	

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Placebo (Placebo)'	Dean Skiles (b) (4)	08 Jan 2021 23:52:15
	(b) (4)	

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 02:03:03
User entered 'Placebo (Placebo)'	Dean Skiles (b) (4)	08 Jan 2021 23:52:15
	(b) (4)	

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 02:03:03
User entered 'Placebo (Placebo)'	Dean Skiles (b) (4)	08 Jan 2021 23:52:15
	(b) (4)	

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Dean Skiles (b) (4)	08 Jan 2021 23:52:15
	(b) (4)	

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered '1'	System	08 Jan 2021 23:52:15

US3012131

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

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'I'	System	08 Jan 2021 23:52:15

US3012131

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '65' in	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '159.8' lb	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User entered '26.64771'	System	09 Jan 2021 01:48:00
DataPoint set to visible.	System	08 Jan 2021 23:52:15

US3012131

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '65' in	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '159.8' lb	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User entered '26.64771'	System	09 Jan 2021 01:48:00
DataPoint set to visible.	System	08 Jan 2021 23:52:15

US3012131

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '8 Jan 2021'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '14:38'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered '8 Jan 2021 14:38'	(b) (4), (b) (6)	09 Jan 2021 01:48:00
	System	

US3012131

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '98.3' F	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Oral (Oral)'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '63'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'bpm'	System	09 Jan 2021 01:48:00

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '14'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Jan 2021 01:48:00

US3012131

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '122'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'mmHg'	(b) (4), (b) (6) System	09 Jan 2021 01:48:00

US3012131

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '74'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'mmHg'	(b) (4), (b) (6) System	09 Jan 2021 01:48:00

US3012131

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '65' in	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '159.8' lb	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User entered '26.64771'	System	09 Jan 2021 01:48:00
DataPoint set to visible.	System	08 Jan 2021 23:52:15

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '8 Jan 2021'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '16:45'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered '8 Jan 2021 16:45'	(b) (4), (b) (6)	09 Jan 2021 01:48:00
	System	

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '98.2' F	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Oral (Oral)'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '80'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'bpm'	System	09 Jan 2021 01:48:00

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '14'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Jan 2021 01:48:00

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '160'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'mmHg'	(b) (4), (b) (6) System	09 Jan 2021 01:48:00

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '70'	Dean Skiles (b) (4)	09 Jan 2021 01:48:00
	(b) (4)	

US3012131

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'mmHg'	(b) (4), (b) (6) System	09 Jan 2021 01:48:00

US3012131

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Dean Skiles (b) (4)	09 Jan 2021 01:48:23
	(b) (4)	

US3012131

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '8 Jan 2021'	Dean Skiles (b) (4)	09 Jan 2021 01:48:23
	(b) (4)	

US3012131

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

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Dean Skiles (b) (4)	09 Jan 2021 01:49:05
	(b) (4)	

US3012131

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

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Dean Skiles (b) (4)	09 Jan 2021 01:49:05
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

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 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Dean Skiles (b) (4)	09 Jan 2021 01:49:05
	(b) (4)	

US3012131

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

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User entered 'mRNA-1273'	System	09 Jan 2021 01:49:05
DataPoint set to visible.	System	08 Jan 2021 23:52:15

US3012131

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

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '8 Jan 2021'	Dean Skiles (b) (4)	09 Jan 2021 01:49:05
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '15:56'	Dean Skiles (b) (4)	09 Jan 2021 01:49:05
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered '8 Jan 2021 15:56'	(b) (4), (b) (6)	09 Jan 2021 01:49:05
	System	

US3012131

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

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Dean Skiles (b) (4)	09 Jan 2021 01:49:05
	(b) (4)	

US3012131

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

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'ONCE'	System	09 Jan 2021 01:49:05

US3012131

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

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	09 Jan 2021 01:49:05

US3012131

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Dean Skiles (b) (4)	08 Jan 2021 23:52:50
	(b) (4)	

US3012131

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '8 Jan 2021'	Dean Skiles (b) (4)	08 Jan 2021 23:52:50
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '15:08'	Dean Skiles (b) (4)	08 Jan 2021 23:52:50
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered '8 Jan 2021 15:08'	(b) (4), (b) (6)	08 Jan 2021 23:52:50
	System	

US3012131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Dean Skiles (b) (4)	08 Jan 2021 23:53:14
	(b) (4)	

US3012131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '8 Jan 2021'	Dean Skiles (b) (4)	08 Jan 2021 23:53:14
	(b) (4)	

US3012131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '14:56'	Dean Skiles (b) (4)	08 Jan 2021 23:53:14
	(b) (4)	

US3012131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered '8 Jan 2021 14:56'	(b) (4), (b) (6)	08 Jan 2021 23:53:14
	System	

US3012131

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

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Dean Skiles (b) (4)	08 Jan 2021 23:53:19
	(b) (4)	

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

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'I'	System	08 Jan 2021 23:53:19

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Jan 2021 23:33:43
	(b) (4)	

US3012131

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '15 Jan 2021'	Jennifer Leyva (b) (4)	15 Jan 2021 23:33:43
	(b) (4)	

US3012131

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jennifer Leyva (b) (4)	15 Jan 2021 23:33:43
	(b) (4)	

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	15 Jan 2021 23:33:43
	(b) (4)	

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Leyva (b) (4)	15 Jan 2021 23:34:21
	(b) (4)	

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'I'	(b) (4), (b) (6) System	15 Jan 2021 23:34:21

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User entered '1'	System	15 Jan 2021 23:34:21
DataPoint set to visible.	System	15 Jan 2021 23:34:21

US3012131

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Lamar Box (b) (4)	08 Feb 2021 21:34:53
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '5 Feb 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 23:11:40
	(b) (4)	
	(b) (4)	
User entered '8 Feb 2021'	Lamar Box (b) (4)	08 Feb 2021 21:34:53
	(b) (4)	

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Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[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 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Clinic (Clinic)'	Lamar Box (b) (4)	08 Feb 2021 21:34:53
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'OLD29'	System	08 Feb 2021 21:34:53

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 23:11:49
User entered '05 Feb 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 23:11:49
	(b) (4)	
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 23:11:40
User entered '8 Feb 2021'	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '11:17'	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User entered '05 Feb 2021 11:17'	System	03 Mar 2021 23:11:49
User entered '8 Feb 2021 11:17'	System	08 Feb 2021 21:35:39

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '98.4' F	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Oral (Oral)'	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '64'	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'bpm'	System	08 Feb 2021 21:35:39

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '14'	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Feb 2021 21:35:39

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '128'	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'mmHg'	(b) (4), (b) (6) System	08 Feb 2021 21:35:39

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '76'	Lamar Box (b) (4)	08 Feb 2021 21:35:39
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'mmHg'	(b) (4), (b) (6) System	08 Feb 2021 21:35:39

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 23:11:49
User entered '05 Feb 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 23:11:49
	(b) (4)	
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 23:11:40
User entered '8 Feb 2021'	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '12:58'	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User entered '05 Feb 2021 12:58'	System	03 Mar 2021 23:11:49
User entered '8 Feb 2021 12:58'	System	08 Feb 2021 21:36:37

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '97.3' F	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Oral (Oral)'	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '64'	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'bpm'	System	08 Feb 2021 21:36:37

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '14'	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Feb 2021 21:36:37

US3012131

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '128'	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'mmHg'	(b) (4), (b) (6) System	08 Feb 2021 21:36:37

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '74'	Lamar Box (b) (4)	08 Feb 2021 21:36:37
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'mmHg'	(b) (4), (b) (6) System	08 Feb 2021 21:36:37

US3012131

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Lamar Box (b) (4)	08 Feb 2021 21:36:50
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 23:11:55
User entered '05 Feb 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 23:11:55
	(b) (4)	
	(b) (4)	
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 23:11:40
User entered '8 Feb 2021'	Lamar Box (b) (4)	08 Feb 2021 21:36:50
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Lamar Box (b) (4)	08 Feb 2021 21:37:16
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Lamar Box (b) (4)	08 Feb 2021 21:37:16
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

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 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Lamar Box (b) (4)	08 Feb 2021 21:37:16
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User entered 'mRNA-1273'	System	08 Feb 2021 21:37:16
DataPoint set to visible.	System	15 Jan 2021 23:34:21

US3012131

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 23:12:16
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	03 Mar 2021 23:12:16
User entered '05 Feb 2021' reason for change: Data Entry Error	Pamela Fidler (b) (4)	03 Mar 2021 23:12:16
	(b) (4)	
	(b) (4)	
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 23:11:40
User entered '8 Feb 2021'	Lamar Box (b) (4)	08 Feb 2021 21:37:16
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '12:23'	Lamar Box (b) (4)	08 Feb 2021 21:37:16
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User entered '05 Feb 2021 12:23'	System	03 Mar 2021 23:12:16
User entered '8 Feb 2021 12:23'	System	08 Feb 2021 21:37:16

US3012131

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Lamar Box (b) (4)	08 Feb 2021 21:37:16
	(b) (4)	

US3012131

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'ONCE'	System	08 Feb 2021 21:37:16

US3012131

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 21:37:16

US3012131

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Lamar Box (b) (4)	08 Feb 2021 21:37:20
	(b) (4)	

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'I'	(b) (4), (b) (6) System	08 Feb 2021 21:37:20

US3012131

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Jessica Ruff (b) (4)	12 Feb 2021 18:29:05
	(b) (4)	

US3012131

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Mar 2021 23:12:16
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	03 Mar 2021 23:12:16
Amendment Manager: User opened query 'OL Safety System Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 00:51:38
User entered '12 Feb 2021'	Jessica Ruff (b) (4)	12 Feb 2021 18:29:05
	(b) (4)	

US3012131

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessica Ruff (b) (4)	12 Feb 2021 18:29:05
	(b) (4)	

US3012131

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Jessica Ruff (b) (4)	12 Feb 2021 18:29:05
	(b) (4)	

US3012131

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Jessica Ruff (b) (4)	12 Feb 2021 18:29:07
	(b) (4)	

US3012131

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'I'	System	12 Feb 2021 18:29:07

US3012131

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:07
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '10 Mar 2021'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:07
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[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 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Clinic (Clinic)'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:07
	(b) (4)	
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'OLD57'	System	10 Mar 2021 21:56:07

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:40
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '10 Mar 2021'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:40
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '10:30'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:40
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered '10 Mar 2021 10:30'	(b) (4), (b) (6)	10 Mar 2021 21:56:40
	System	

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '98.8' F	Pamela Fidler (b) (4)	10 Mar 2021 21:56:40
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Oral (Oral)'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:40
	(b) (4)	
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Pamela Fidler (b) (4)	10 Mar 2021 21:56:40
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '71'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:40
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'bpm'	System	10 Mar 2021 21:56:40

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '16'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:40
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'breaths/min'	System	10 Mar 2021 21:56:40

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '108'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:40
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'mmHg'	(b) (4), (b) (6) System	10 Mar 2021 21:56:40

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '72'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:40
	(b) (4)	
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered 'mmHg'	(b) (4), (b) (6) System	10 Mar 2021 21:56:40

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	

US3012131

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	

US3012131

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'No (N)'	Pamela Fidler (b) (4)	10 Mar 2021 21:56:42
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered empty.	Pamela Fidler (b) (4)	10 Mar 2021 21:56:42
	(b) (4)	
	(b) (4)	

US3012131

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	10 Mar 2021 21:57:35
	(b) (4)	
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '10 Mar 2021'	Pamela Fidler (b) (4)	10 Mar 2021 21:57:35
	(b) (4)	
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
	(b) (4), (b) (6)	
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
User entered '10:39'	Pamela Fidler (b) (4)	10 Mar 2021 21:57:35
	(b) (4)	
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:59:09
User entered '10 Mar 2021 10:39'	(b) (4), (b) (6)	10 Mar 2021 21:57:35
	System	

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:46:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:53:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:06:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:34:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4)	14 Dec 2020 22:25:03
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 16:00:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:06:56
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered	(b) (4)	15 Dec 2020 16:27:09
'USA-US006-2020-mRNA-1273-P301000004'	System	15 Dec 2020 16:27:09
User entered 'New'	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 16:27:09
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:06:58
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	14 Dec 2020 22:27:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 22:27:04
Data point term sent to Coder	System	14 Dec 2020 22:26:20
User entered 'Stroke'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:01
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'Yes (Y)'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:03
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:08
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:10
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered '11 Dec 2020'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered empty.	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 22:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:13
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'No (N)'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:14
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered '11 Dec 2020'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:17
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered empty.	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 22:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:19
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

US3012131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:22
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	14 Dec 2020 22:32:11
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Dec 2020 22:25:56
User entered 'Yes (Y)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:24
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered '0'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:38
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered '0'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

US3012131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:40
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Mar 2021 19:34:24
	(b) (4)	
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		14 Dec 2020 22:32:26
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		14 Dec 2020 22:32:26
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	14 Dec 2020 22:32:11
User entered '1' reason for change: Data Entry Error	Pamela Fidler (b) (4)	14 Dec 2020 22:32:11
	(b) (4)	
	(b) (4)	
User entered '0'	Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:41
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:32:11
User entered empty.	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:43
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User closed query 'PV Query: Please provide the discharge summary for this hospitalization.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Dec 2020 14:34:31
Query 'PV Query: Please provide the discharge summary for this hospitalization.' answered with 'Pending. Requested x2' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	21 Dec 2020 18:39:11
User opened query 'PV Query: Please provide the discharge summary for this hospitalization.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Dec 2020 18:35:51
User entered '13 Dec 2020' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4)	14 Dec 2020 22:32:11
User entered empty.	(b) (4) Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:44
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:32:26
User entered empty.	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:46
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered empty.	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:47
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered '0'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:49
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered '0'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:51
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered '0'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:53
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'Not Related (NOT RELATED)'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:54
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'Not Related (NOT RELATED)'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:56
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:07:58
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered '0'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:08:00
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'I'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:08:02
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered '0'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:08:04
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:08:05
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User entered empty.	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:25:56
	(b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:08:08
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	12 Mar 2021 19:34:24
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. PLEASE LEAVE QUERY OPEN UNTIL INFORMATION IS AVAILABLE.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:09:50
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. PLEASE LEAVE QUERY OPEN UNTIL INFORMATION IS AVAILABLE.' answered with 'Emailed to Safety_Moderna@iqvia.com on 06-Jan-2021' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	06 Jan 2021 23:33:38
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. PLEASE LEAVE QUERY OPEN UNTIL INFORMATION IS AVAILABLE.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Jan 2021 15:11:36
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. PLEASE LEAVE QUERY OPEN UNTIL INFORMATION IS AVAILABLE.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 16:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. PLEASE LEAVE QUERY OPEN UNTIL INFORMATION IS AVAILABLE. ' answered with 'Site fax machine broken. Awaiting delivery of records by subject. AGAINST SITE POLICY TO LEAVE QUERIES OPEN FOR UNSPECIFIED AMOUNT OF TIME. ' (Site from Safety).	Jennifer Leyva (b) (4)	30 Dec 2020 23:49:23
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. PLEASE LEAVE QUERY OPEN UNTIL INFORMATION IS AVAILABLE. ' (Site from Safety).	(b) (4), (b) (6)	26 Dec 2020 18:47:15
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 12:43:47
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Will send once received at site.' (Site from Safety).	Jennifer Leyva (b) (4)	22 Dec 2020 22:59:55
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 22:56:51
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:34:46

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
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) (b) (4), (b) (6)	22 Dec 2020 14:34:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'None' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	21 Dec 2020 18:39:25
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'None.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	21 Dec 2020 18:39:21
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Dec 2020 18:35:23
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Dec 2020 18:35:08
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 22:34:21
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Dec 2020 22:34:21
User entered 'Pt reported she had a stroke in the mid morning and rushed to the ER. She was given an injection of Tenecteplase and observed until the morning of 13DEC2020' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:34:21
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 22:25:56
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 22:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 22:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Dec 2020 22:32:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:53:11
User closed query 'Per source, ConMed of Clindamycin with 08Mar2021 start date is recorded. Please verify and add to EDC.' (Site from CRA).	(b) (4), (b) (6)	(b) (4), (b) (6)
Query 'Per source, ConMed of Clindamycin with 08Mar2021 start date is recorded. Please verify and add to EDC.' answered with 'Updated' (Site from CRA).	Pamela Fidler (b) (4)	16 Apr 2021 21:12:36
User opened query 'Per source, ConMed of Clindamycin with 08Mar2021 start date is recorded. Please verify and add to EDC.' (Site from CRA).	(b) (4)	16 Apr 2021 14:39:44
User signature succeeded.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	(b) (4), (b) (6)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 21:06:32
	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
	(b) (4)	
	(b) (4), (b) (6)	(b) (4), (b) (6)
	(b) (4), (b) (6)	13 Jan 2021 17:10:43
	Jennifer Leyva (b) (4)	31 Aug 2020 15:51:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DOXEPIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Aug 2020 15:54:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:54:30
Data point term sent to Coder	System	31 Aug 2020 15:53:38
User entered 'doxepin'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'insomnia'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '10'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'UN UNK 2015'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 15:53:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Sep 2020 02:27:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:27:44
Data point term sent to Coder	System	31 Aug 2020 15:54:38
User entered 'gabapentin'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'nerve pain, due to reflux sympathetic dystrophy'	(b) (4) Jennifer Leyva (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '400'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'UN UNK 2015'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 15:53:57

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: TIMOLOL MALEATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 15:06:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:06:43
Data point term sent to Coder Coding entries removed.	System Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:13:22 22 Sep 2020 00:12:30
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: TIMOLOL MALEATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:09:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:09:36
Data point term sent to Coder User entered 'timolol maleale'	System Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:40 31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 07:38:00
User closed query 'Per DM CLR: Please update the indication to reflect the laterality of glaucoma. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 07:37:18
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MH added' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:13:16
Query 'Per DM CLR: Please update the indication to reflect the laterality of glaucoma. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:12:34
User entered 'GLAUCOMA, bilateral' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:12:30
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 06:40:20
User opened query 'Per DM CLR: Please update the indication to reflect the laterality of glaucoma. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 06:40:09
User entered 'glaucoma'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '6.8'	(b) (4) Jennifer Leyva (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'UN UNK 2019'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 15:55:14

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 00:15:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 00:15:52
Data point term sent to Coder Coding entries removed.	System Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:14:23 22 Sep 2020 00:14:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:57:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:57:38
Data point term sent to Coder User entered 'prolia'	System Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:41 31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'osteoporosis'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '60'	(b) (4) Jennifer Leyva (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'other (OTHER)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Q6M'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 07:38:34
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:14:20
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:14:18
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 05:07:18
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'UN UNK 2016'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 15:55:52

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OCULAR VASCULAR DISORDER AGENTS, ATC: ANTINEOVASCULARISATION AGENTS, PRODUCT: AFLIBERCEPT, PRODUCTSYNONYM: EYLEA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 06:25:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 06:25:44
Data point term sent to Coder Coding entries removed.	System Jennifer Leyva (b) (4)	22 Sep 2020 00:16:24 22 Sep 2020 00:15:36
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OCULAR VASCULAR DISORDER AGENTS, ATC: ANTINEOVASCULARISATION AGENTS, PRODUCT: AFLIBERCEPT, PRODUCTSYNONYM: EYLEA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 09:43:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 09:43:48
Data point term sent to Coder User entered 'eylea'	System Jennifer Leyva (b) (4)	31 Aug 2020 15:56:44 31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'macular degeneration, bilateral'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'I'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Other (OTHER)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'injection'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'other (OTHER)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Q6W'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Intravitreal). Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 07:38:48
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Intravitreal). Please update route as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:15:38
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:15:36
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Intravitreal). Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 06:03:43
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'intravitreal' reason for change: Data Entry Error	(b) (4)	
	Jennifer Leyva (b) (4)	22 Sep 2020 00:15:36
	(b) (4)	
User entered empty.	Jennifer Leyva (b) (4)	31 Aug 2020 15:56:33
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'UN UNK 2016'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 15:56:33

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
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)	31 Aug 2020 15:58:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:58:38
Data point term sent to Coder	System	31 Aug 2020 15:57:45
User entered 'Vitamin D3'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'osteoporosis'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '50000'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'IU (IU)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'every week (QS)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'UN UNK 2016'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	31 Aug 2020 15:57:06

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CITRATE;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM CITRATE VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 16:15:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 16:15:38
Data point term sent to Coder	System	31 Aug 2020 15:57:47
User entered 'calcium citrate / D3'	Jennifer Leyva (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'osteoporosis'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '630'	(b) (4) Jennifer Leyva (b) (4)	31 Aug 2020 15:57:35
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'UN UNK 2016'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 15:57:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	29 Sep 2020 15:37:45
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 Sep 2020 15:37:45
Data point term sent to Coder	System	11 Sep 2020 15:13:06
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	11 Sep 2020 15:12:56
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated with general term as there are over 20 ingredients in med.' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 15:12:56
User entered 'OCUVITE (multivitamin/minerals)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	11 Sep 2020 15:12:26
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	03 Sep 2020 09:04:33
Data point term sent to Coder	System	31 Aug 2020 15:58:52
User entered 'ocuvite'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'macular degeneration, bilateral'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'I'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'tablet (TABLET)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'UN UNK 2016'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 15:58:09

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Aug 2020 16:26:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:26:13
Data point term sent to Coder	System	31 Aug 2020 16:13:51
Data point term sent to Coder	System	31 Aug 2020 15:59:53
User entered 'B-Complex'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'chronic FATIGUE' reason for change:	(b) (4)	
Data Entry Error	Jennifer Leyva (b) (4)	31 Aug 2020 16:13:06
User entered 'fatigue'	(b) (4)	
	Jennifer Leyva (b) (4)	31 Aug 2020 15:58:54
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '1'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'tablet (TABLET)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'UN UNK 2016'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 15:58:54

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Aug 2020 16:00:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 16:00:41
Data point term sent to Coder	System	31 Aug 2020 15:59:56
User entered 'acetaminophen'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 07:39:43
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MH added' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	22 Sep 2020 00:14:51
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 04:42:48
User entered 'general myalgias'	Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '1000'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'mg (mg)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'once daily (QD)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Oral (ORAL)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'UN Jul 2019'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4) (b) (4)	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 15:59:31

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
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) (b) (4)	14 Oct 2020 20:05:32
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 Oct 2020 20:05:32
Data point term sent to Coder	System	14 Oct 2020 20:04:20
User entered 'influenza vaccine'	Katherine Davis (b) (4) (b) (4)	14 Oct 2020 20:03:53

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Yes (Y)'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'influenza prophylaxis'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'I'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Other (OTHER)'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'shot'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'once (ONCE)'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '28 Sep 2020'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '0'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered '28 Sep 2020'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Katherine Davis (b) (4)	14 Oct 2020 20:03:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 20:03:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 20:03:53

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 11:01:28
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 20:03:53

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: TENECTEPLASE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:40:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 14:40:09
Data point term sent to Coder Coding entries removed.	System Pamela Fidler (b) (4) (b) (4)	16 Apr 2021 14:38:42 16 Apr 2021 14:38:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: TENECTEPLASE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 11:03:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 11:03:06
Data point term sent to Coder Coding entries removed.	System Pamela Fidler (b) (4) (b) (4)	25 Jan 2021 18:13:26 25 Jan 2021 18:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:11:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: TENECTEPLASE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 23:06:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 23:06:43
Data point term sent to Coder	System	14 Dec 2020 22:29:23

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Tenecteplase'	Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:11:08
User entered 'No (N)'	(b) (4), (b) (6) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:11:09
User entered 'Stroke'	(b) (4), (b) (6) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:01:18
User signature succeeded.	(b) (4), (b) (6)	
	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	15 Jan 2021 12:36:27
Query 'Per DM CLR: Please provide the actual dose for this medication instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Unknown' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	13 Jan 2021 21:36:24
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 04:09:47
User entered 'I'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:19

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:01:20
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Other (OTHER)'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:01:22
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'Injection'	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:11:41
User entered 'once (ONCE)'	(b) (4), (b) (6) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:11:43
User entered empty.	(b) (4), (b) (6) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 21:12:17
User closed query 'Per source, route of administration is recorded as, Intramuscular. Please verify and update EDC/Source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 21:12:15
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
Query 'Per source, route of administration is recorded as, Intramuscular. Please verify and update EDC/Source accordingly.' answered with 'Updated' (Site from CRA).	(b) (4)	16 Apr 2021 14:38:57
Signature has been broken.	Pamela Fidler (b) (4)	16 Apr 2021 14:38:34
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	(b) (4)	16 Apr 2021 14:38:34
User opened query 'Per source, route of administration is recorded as, Intramuscular. Please verify and update EDC/Source accordingly.' (Site from CRA).	Pamela Fidler (b) (4)	13 Apr 2021 21:01:58
User signature succeeded.	(b) (4)	26 Mar 2021 00:52:46
User closed query 'Per DM CLR-RQ: Response noted. However, please re-review as intramuscular is not the usual route, consider updating route (eg, intravenous). Else, re-confirm/clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Jan 2021 15:59:06
Query 'Per DM CLR-RQ: Response noted. However, please re-review as intramuscular is not the usual route, consider updating route (eg, intravenous). Else, re-confirm/clarify.' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	25 Jan 2021 18:13:18
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 18:13:12
User opened query 'Per DM CLR-RQ: Response noted. However, please re-review as intramuscular is not the usual route, consider updating route (eg, intravenous). Else, re-confirm/clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Jan 2021 06:53:43

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	(b) (4), (b) (6) 24 Jan 2021 06:53:43
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Patient reported receiving drug in form of injection' (Site from DM).	Jennifer Leyva (b) (4)	13 Jan 2021 21:36:38
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	(b) (4), (b) (6) 13 Jan 2021 04:10:32
User entered 'Intramuscular (INTRAMUSCULAR)'	Pamela Fidler (b) (4)	14 Dec 2020 22:29:19

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:02:00
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered empty.	(b) (4) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:11:54
User entered '11 Dec 2020'	(b) (4), (b) (6) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:11:57
User entered '0'	(b) (4), (b) (6) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:11:59
User entered 'No (N)'	(b) (4), (b) (6) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:12:00
User entered '11 Dec 2020'	(b) (4), (b) (6) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:12:02
User entered 'No (N)'	(b) (4), (b) (6) Pamela Fidler (b) (4)	14 Dec 2020 22:29:19
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User entered empty.	(b) (4), (b) (6) System	14 Dec 2020 22:29:19

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User entered empty.	(b) (4), (b) (6) System	14 Dec 2020 22:29:19

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:16:26
User entered empty.	(b) (4), (b) (6) System	14 Dec 2020 22:29:19

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:12:09
	(b) (4), (b) (6)	
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: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 22:39:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 22:39:55
Data point term sent to Coder	System	14 Dec 2020 22:30:23
User entered 'Baby Aspirin'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:12:11
User entered 'Yes (Y)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 14:50:18
	(b) (4), (b) (6)	
User closed query 'Per progress notes, patient was advised to take baby aspirin following stroke. Please confirm that this is the correct indication. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 14:50:15
Query 'Per progress notes, patient was advised to take baby aspirin following stroke. Please confirm that this is the correct indication. ' answered with 'Correct as entered. Subject was advised by PCP to take baby aspirin prophylactically for cardiac health post Stroke.' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Jan 2021 21:37:23
User opened query 'Per progress notes, patient was advised to take baby aspirin following stroke. Please confirm that this is the correct indication. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:33
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:12:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:12:13
User entered 'Cardiac Prophylaxis'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:38
User entered '81'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:40
User entered 'mg (mg)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:42
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:44
User entered 'once daily (QD)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:46
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:48
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:50
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:56
User entered '13 Dec 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:57
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:13:59
User entered 'Yes (Y)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:01
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:03
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 22:29:55

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 09:53:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 09:53:48
Data point term sent to Coder	System	13 Jan 2021 21:38:01
Coding entries removed.	Jennifer Leyva (b) (4)	13 Jan 2021 21:37:46
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 23:47:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 23:47:48
Data point term sent to Coder	System	14 Dec 2020 22:31:26
User entered 'Pepcid (famotidine)'	Pamela Fidler (b) (4)	14 Dec 2020 22:30:39
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:18
User entered 'Yes (Y)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:03:27
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	15 Jan 2021 12:37:19
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	13 Jan 2021 21:37:52
User entered 'PROPHYLAXIS after episode of CVA/Stroke' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Jan 2021 21:37:46
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 04:11:00
User entered 'Prophylaxis'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:21
User entered '20'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:22
User entered 'mg (mg)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:25
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:26
User entered 'once daily (QD)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:28
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:30
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:32
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:37
User entered '13 Dec 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:39
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:42
User entered 'Yes (Y)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:46
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:14:48
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 22:30:39

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:06:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:06:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	16 Apr 2021 15:22:15
Data point term sent to Coder	System	16 Apr 2021 14:40:59
User entered 'Clyndimycin'	Pamela Fidler (b) (4) (b) (4) (b) (4)	16 Apr 2021 14:40:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered 'No (N)'	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered 'Tooth Infection'	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered '300'	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered 'mg (mg)'	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered empty.	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
	(b) (4)	
User entered 'three times daily (TID)'	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered empty.	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered 'Oral (ORAL)'	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered empty.	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

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

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered '08 Mar 2021'	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered '0'	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered 'Yes (Y)'	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered empty.	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	16 Apr 2021 15:22:15
User entered 'No (N)'	(b) (4)	
	Pamela Fidler (b) (4)	16 Apr 2021 14:40:35
	(b) (4)	
	(b) (4)	

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 14:40:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:40:35

US3012131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 14:40:35

US3012131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:46:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 21:00:39
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	26 Mar 2021 00:52:46
User entered 'No (N)'	(b) (4) Jennifer Leyva (b) (4)	31 Aug 2020 16:00:21
	(b) (4)	

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:07:56
User entered 'USA-US006-2020-MRNA-1273-P301000004'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:07:58
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:07:59
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:01
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:22
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:24
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:38
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:40
User entered 'Laurence'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:42
User entered 'Chu'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:43
User entered '3100 Red River Street'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:45
User entered 'Austin'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:47
User entered 'TX'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:49
User entered '78705'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:51
User entered 'US'	(b) (4), (b) (6) System	15 Dec 2020 16:27:32

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Dec 2020 16:27:32

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:07:56
User entered 'USA-US006-2020-MRNA-1273-P301000004'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:07:58
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:07:59
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:01
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:22
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:24
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:38
User entered 'No (N)'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:40
User entered 'Laurence'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:42
User entered 'Chu'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:43
User entered '3100 Red River Street'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:45
User entered 'Austin'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:47
User entered 'TX'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:49
User entered '78705'	(b) (4), (b) (6) System	15 Dec 2020 16:27:09

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:08:51
User entered 'US'	(b) (4), (b) (6) System	15 Dec 2020 16:27:32

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Dec 2020 16:27:32

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:46:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:09:08
User entered '15/Dec/2020 11:27'	(b) (4), (b) (6) System	15 Dec 2020 16:27:32

US3012131

Folder: SAE USA-US006-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:46:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Laurence Chu (b) (4)	26 Mar 2021 00:52:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:09:20
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 16:27:38
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 16:27:32
	(b) (4), (b) (6)	